83-2093

No.

In the Supreme Court of the United States

October Term, 1983

E. R. Squibb & Sons, Inc.,
Petitioner,

vs.

Gail Abel, Randee Adler, Jo Ann Alexander, Joe G. Alexander, Dian Alpert, Diane Amorose, Joan Archie, Lori Arsenault, Dana Avrunin, Joyce Babcock, Susan Barenholtz, Lynne Bednowitz, Sharon Beeckler, Thomas F. Beeckler, Mirilyn Berg, Allen Berg, Merle A. Bernberg, Nancy Bernstein, Lisa Bovitz, Laurie Brandt, Doreen Braverman, Toni Beth Brenner, Karen Brodley, Helene Cheryl Brody, Jay Howard Brody, Karen Buell, Christine Bump, Michael H. Bump, Barbara F. Burmeister, Richard H. Burmeister, Christine Cloyd, Michael Cloyd, Robin Cohen, John Cohen, Donna Coppess, James Coppess, Laurie Dawson, Robert Dawson, Caroline DeMare, Suzanne Engelberg, Jeannette Evans, Ronald Evans, Lois Fulgenzi, Geraldine Ann Fuller, Sharon Gaines, Donald Gaines, Gayle Ginsburg, Karen B. Ginsburg, Linda Gislason, John Gislason, Sheila Glantz, Ellen Glovinsky, Lisa Glovinsky, Linda Goldenberg, Murray Goldenberg, Terri Goren, Wendy Goren, Amy Gorman, Caryn Green, Maureen Grenwald, Ivy Grossman, Patricia Hacht, Lori Ann Hanna, Jody Hayes, Eileen Heideman, Howard Heideman, Faith Ann Henderson, Larry Henderson, Audrey Herman, Helena Herman, Barbara Herzoff, Lois Hill, Sally Hoben, Debra Hooberman, Peggy Hooberman, Sheridan Hudson, Sherry Lynn Hunt, Rodney Hunt, Joyce Keller, Gail Frances Kelman, Rochelle Kramer, Sherrill Kurland, Diane P. Lenk, Richard M. Lenk, Lynne Levine, Jerold Levine, Lisa Levit, Sandra Lindrus, Elyse Madgy, Harriet Marcet, Mark Marcet, Marla Beth Matz, Susan Mayho, Deborah Mazer, Marc Mazer, Debra McCloskey, Jennifer McVean, Lori Mehler, Susan Mehler, Susan Meister, Thomas L. Meister, Beverly Metropoulos, Susan Miller, Marla Morochnick, Jacqueline Odom, Randall Odom, Francesca O'Grady, Patrick O'Grady, Donna Olsen, Richard Olsen, Debra L. Olshansky, Linda C. Patten, Joyce Paul, Barbara Pickens, Sheri L. Pickens, Jaye Pojanski, Frances Ellen Ross

(Cover Sheet Continued on Inside Cover Page)

E. L. MENDENHALL, INC., 926 Cherry Street, Kansas City, Mo. 64106, (816) 421-3030

Rassler, Richard Rassler, Barbara Respecki, Laura Ann Rose, Susan Rose, Gail Sampson, Wendy Schwartz, Linda Sciturro, Philip Sciturro, Crystal Gamble Scott, Walter Louis Scott, Andrea Sellers, Judith Share, Inez Shearer, Robert Shearer, Joan Sherman, Denise Shpargel, Cynthia Siefman, Sheila Silber, Cathy Silverman, Deborah Silverman, Lori Ann Simon, Valerie Skomra, Marie Smith, Paul Smith, Diane Smola, Susan Spevak, Debra Stasson, Catherine Stevens, Elyse Sutherland, Beverly Tapper, Andrea Tarnoff, Barbara Tarnoff, Cindy Tarnoff, Debra Tarnoff, Lynn Tarnoff, Marsha Lynn Tatarka, Andrea Tolle, Gerald Tolle, Lucette Ann Travers, Patricia H. Travers, Sharon Uherek, Frank Uherek, Jennifer Vandervennet, Ellen Victor, Karen Walkon, Clifford Walkon, Marylou Warnke, Robert Warnke, Susan Weider, Benjamin Weider, Naureen Weinger, Sharon Labelle Whiteman, Alan Whiteman, Deborah Wietecha, Anna Maria Willson, Edie Lynn Wolk, Robert L. Wolk, Susan Yenofsky, Christine Zadow, Louis Zadow, Susan Zaff, Sheryl Zeiger, Harold Zeiger, Denise Zimmerman, Don L. Zimmerman, Eli Lilly Company, Abbott Laboratories, The Blue Line Chemical Company, Burroughs Wellcome Company, Central Pharmacal Company, Cole Pharmacal Company, Kremers-Urban Company, McNeil Laboratories, Inc., Merck, Sharpe & Dohme, Rexall Drug Company, William H. Rorer, Inc., S. J. Tutag & Co., Inc., Schering Corporation, Upjohn Company, and Vale Chemical Company,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF MICHIGAN

PLUNKETT, COONEY, RUTT, WATTERS,
STANCZYK & PEDERSEN, P.C.
JOHN P. JACOBS (Counsel of Record)
900 Marquette Building
Detroit, Michigan 48226
Phone: (313) 965-3900

Attorney for Petitioner, E. R. Squibb & Sons, Inc.

HAIGHT, DICKSON, BROWN & BONESTEEL
2800 Twenty-Eighth Street
Santa Monica, California 90404-0132
Phone: (213) 450-6001

QUESTIONS PRESENTED

1. Whether a state takes property without due process of law in contravention of the Fourteenth Amendment of the Constitution of the United States by the adoption of a rule of products liability, unique to manufacturers of synthetic estrogens, which relieves claimants of the usual burden of proof of identifying a product and which imposes tort liability on such manufacturers, even if the injured parties are unable to prove that their injuries were caused by exposure to a specific product attributable to an identifiable manufacturer.

2. Whether a state violates due process of law under the Fourteenth Amendment of the Constitution of the United States by the imposition of a products liability procedural rule which transfers to the manufacturers the inability of claimants to prove exposure to a specific product or to identify its manufacturer when, in many cases, the manufacturers will be equally unable to rebut or disprove such exposure, and when the effect of such a burden-shifting presumption is to impose damages upon the manufacturers and distributors without the showing of any specific causal involvement with the product.

3. Whether a state violates the equal protection of laws clause of the Fourteenth Amendment of the Constitution of the United States by creating a one-product form of tort liability, unique to one drug, by which the state denies numerous substantive and procedural legal rights and guarantees to such manufacturers but which are available to every other manufacturer or distributor of all other products.

LIST OF PARTIES

All of the parties appearing in the litigation before the Michigan Supreme Court are identified and set forth in the caption of this Petition. The individuals were the plaintiffs below; the corporations were named as defendants below. For the sake of convenience, those individual respondents who were claimants below shall be referred to as "plaintiffs"; those corporate respondents who were manufacturers or distributors below shall be referred to as "defendants".

TABLE OF CONTENTS

Questions Presented III
List of Parties IV
Table of Authorities VII
Opinions Below 1
Jurisdiction 1
Constitutional Provisions Involved 2
Statement of the Case 2
Reasons for Allowance of the Writ 9
Argument—
Argument I. The *Abel* Rule Establishes Civil Products Liability Without a Prior Showing of Tort Fault and Is a Taking of Petitioner's Property Without Due Process of Law 12
Argument II. The *Abel* Rule Creates an Irrebuttable Presumption Which Destroys the "Roughly Equal" Allocation of Burden of Proof in Civil Cases and Which Laterally Transfers the Burden of Products Liability Proof Upon an Irrational Premise Which Violates Petitioner's Rights to Due Process 15
Argument III. The *Abel* Rule Strips Away Numerous Valuable Substantive and Procedural Rights Available to All Other Michigan Products Liability Defendants, and in Doing So, Deprives Petitioner of Equal Protection of the Laws 21
Conclusion 29

INDEX TO APPENDICES

A. Opinion of the Supreme Court of Michigan, dated February 6, 1984 ..... A1

B. Judgment Order of Supreme Court of Michigan Pursuant to Opinion, dated March 26, 1984 and April 27, 1984 Certification of Judgment Order A30

C. Order Denying Rehearing, Supreme Court of Michigan, dated March 26, 1984 ..... A33

D. Opinion of the Michigan Court of Appeals, dated December 5, 1979 ..... A35

E. Order Pursuant to Opinion of the Michigan Court of Appeals, dated March 11, 1980 ..... A64

F. Defendants' Joint Brief in Support of Joint Motion for Summary Judgment, Circuit Court for the County of Wayne (excerpt p. 37) A65

G. Defendants' Joint Reply Brief on Summary Judgment, Circuit Court for the County of Wayne (excerpt pp. 47-51) A66

H. Defendants' Brief on Appeal to Michigan Court of Appeals (excerpt pp. 46, 120-124) A72

I. Defendants' Brief on Appeal, Supreme Court of Michigan (excerpt pp. 47-49) A78

J. Defendant E. R. Squibb & Sons, Inc.'s Brief in Support of Motion for Rehearing, Supreme Court of Michigan (excerpt pp. 12-43) A81

K. Trial Court Affidavits of Jerome Maas, M.D. Filed in the Circuit Court for the County of Wayne A113

L. Excerpts of Questionnaires of Plaintiffs filed in the Circuit Court for the County of Wayne A120

M. Defendants' Brief on Appeal, Regarding History of Synthetic Estrogens, Supreme Court of Michigan (excerpt pp. 1-9) A128

N. Portions of Defendant E. R. Squibb & Sons, Inc.'s Appendix, Supreme Court of Michigan,

1. Deposition of Don Carlos Hines, Wayne County Circuit Court A137
2. Answers to Requests for Admissions by E. R. Squibb & Sons, Inc., Wayne County Circuit Court A171
3. Deposition of Dr. Theodore G. Klumpp, Wayne County Circuit Court A172

TABLE OF AUTHORITIES

Cases

Abel v. *Eli Lilly Co., et al,* 418 Mich. 311, 343 N.W.2d 164 (1984) ..... 1, *passim*

Abel v. *Eli Lilly Co., et al,* 94 Mich. App. 59, 289 N.W.2d 20 (1979) ..... 1, *passim*

Addington v. *Texas,* 441 U.S. 418, 423 (1979) 20, 21

Alabama Great Southern Railroad Co. v. *Allied Chemical Corp.,* 501 F.2d 94, 99, 100 (C.A. 5, 1974), *reh. den.* 509 F.2d 539 (1974) 17

American Motorists Insurance Co. v. *Starnes,* 425 U.S. 637, 642 n. 3 (1976) 8

American Surety Co. v. *Baldwin,* 287 U.S. 156, 158 (1932) 16

Barrows v. *Jackson,* 346 U.S. 249 (1953) 28

Bell v. *Burson,* 402 U.S. 535 (1971) 18, 19

Bichler v. *Eli Lilly Co.,* 436 N.Y.S.2d 625 (1981), *aff'd* 436 N.E.2d 182 12

Bishop v. *Plumb,* 363 Mich. 87, 90, 108 N.W.2d 813, 814 (1961) 13

Bondini Petroleum Co. v. *Superior Court, Los Angeles County, California*, 284 U.S. 8, 19 (1931) 16
Borel v. *Fibreboard Products*, 493 F.2d 1076, 1094-1096 (C.A. 5, 1973), *cert. den.* 419 U.S. 869 12
Bowerman v. *Detroit Free Press*, 279 Mich. 480, 489-490, 272 N.W. 876, 880 (1937) 13
Brinkerhoff-Farris Trust & Savings Co. v. *Hill*, 281 U.S. 673, 680 (1930) 13
Caldwell v. *Fox*, 394 Mich. 401, 410, 231 N.W.2d 46, 50 (1975) 10
Carrington v. *Rash*, 380 U.S. 89 (1965) 19
City of New Orleans v. *Dukes*, 427 U.S. 297, 304 (1976) 28
Cleveland Board of Education v. *LaFleur*, 414 U.S. 632 (1974) 17, 19
Cole v. *State of Arkansas*, 333 U.S. 196, 201 (1948) 14
Collins v. *Eli Lilly Co.*, 116 Wis.2d 166, 342 N.W.2d 37 (1984), *certiorari pending* 12
County Court of Ulster County v. *Allen*, 442 U.S. 140, 157 (1979) 19
Cox Broadcasting Corp. v. *Cohn*, 420 U.S. 469, 476-87 (1975) 8
Dandridge v. *Williams*, 397 U.S. 471, 487 (1969) 27
Diekevers v. *SCM Corp.*, 73 Mich. App. 78, 250 N.W. 2d 548 (1976) 24
Douglas v. *State of California*, 372 U.S. 353 (1963) 28
Draper v. *State of Washington*, 372 U.S. 487 (1963) 29
Duhame v. *Kaiser Engineering of Michigan, Inc.*, 102 Mich. App. 68, 300 N.W.2d 737 (1980) 24
Eskridge v. *State of Washington*, 357 U.S. 214 (1958) 28-29
Ferguson v. *Skupra*, 372 U.S. 726, 732 (1963) 28
Fuentes v. *Shevin*, 407 U.S. 67 (1972) 9

Galvan v. *Press*, 347 U.S. 522 (1954) 13
Glona v. *American Guarantee & Liability Ins. Co.*, 391 U.S. 73 (1968) 28
Griffin v. *State of Illinois*, 351 U.S. 12 (1956) 28
Hall v. *E. I. Dupont de Nemours & Co.*, 345 F. Supp. 353 (D.C. N.Y., 1972) 11-12
Harris v. *United States*, 404 U.S. 1232, 1233 (1971) (Opinion of Douglas, J.) 14
Harris v. *Washington*, 404 U.S. 55, 56 (1971) 8
Heckel v. *American Coupling Corp.*, 384 Mich. 19, 21, 22, 179 N.W.2d 381 (1970) 10
Heiner v. *Donnon*, 285 U.S. 312, 329 (1932) 15, 18
Holden v. *Hardy*, 169 U.S. 366 (1898) 13
In Re Certified Questions, Karl v. *Bryant Air Conditioning Co.*, 416 Mich. 558; 331 N.W.2d 456 (1982) 23
Ingram v. *Interstate Motor Freight Systems, Inc.*, 115 Mich. App. 559, 321 N.W.2d 731 (1982) 24
Insurance Co. of North America v. *Forty-Eight Insulations, Inc.*, 633 F.2d 1212, 1216, fn. (3), 1225 (C.A. 6, 1980), *cert. den.* 454 U.S. 1109 11
Johnson v. *State of Florida*, 385 U.S. 39, 44 (1966) 14
Keil v. *Eli Lilly Co.*, 490 F.Supp. 479 (D.C. Mich., 1980) 23
Lassiter v. *Dept. of Social Services of Durham County, North Carolina*, 452 U.S. 18 (1981) 13
Leary v. *United States*, 395 U.S. 6, 36 (1969) 17
Levy v. *Louisiana*, 391 U.S. 68 (1968) 28
Lindsey v. *Normet*, 405 U.S. 56, 67 (1972) 16, 27-28
Local 438 Construction & General Laborers' Union, AFL-CIO v. *Curry*, 371 U.S. 542 (1963) 8
Lugar v. *Edmonson Oil Co.*, 457 U.S. 922 (1982) 9
Matthews v. *Eldridge*, 424 U.S. 319 (1976) 20

Mercantile National Bank v. *Langdeau*, 371 U.S. 555, 557-58 (1963) 9
Michigan Central Railroad Co. v. *Mix*, 278 U.S. 492 (1929) 8
Minster Machine Co. v. *Diamond Stamping Co.*, 72 Mich. App. 58, 248 N.W.2d 676 (1976) 24
Mobile, Jackson & Kansas City Railroad Co. v. *Turnipseed*, 219 U.S. 35, 43 (1910) 17
Namm v. *Charles E. Frosst & Co., Inc.*, 178 N.J. Super. 19, 427 A.2d 1121, 1128 (1981) 11
Nickey v. *State of Mississippi*, 292 U.S. 393, 396 (1934) 16
North Georgia Finishing, Inc. v. *Di-Chem, Inc.*, 419 U.S. 601 (1975) 9
Ortwein v. *Schwab*, 410 U.S. 656 (1973) 27
Piercefield v. *Remington Arms*, 375 Mich. 85, 98-99, 133 N.W.2d 129 (1965) 10
Rees v. *Watertown*, 86 U.S. (19 Wall.) 107, 122 (1874) 16
Rinaldi v. *Yaeger*, 384 U.S. 305, 310-311 (1966) 28
Santosky v. *Kramer*, 455 U.S. 745 (1982) 21, 22
Shaffer v. *Heitner*, 433 U.S. 186, 195 n. 12 (1977) 8
Sindell v. *Abbott Laboratories*, 26 Cal.3d 588, 603, 163 Cal.Rptr. 132, 607 P.2d 924, *cert. den.* 449 U.S. 912 (1980) 11, 12, 23
Slochower v. *Board of Higher Education of New York City*, 350 U.S. 551 (1956) 13
Snadiach v. *Family Finance Corp.*, 395 U.S. 337 (1969) 9, 13
Stanley v. *State of Illinois*, 405 U.S. 645 (1972) 17, 19
Summers v. *Tice*, 33 Cal.2d 80, 199 P.2d 1 (1948) 4, 10, 21
Swindlehurst v. *Resistance Welder Corp.*, 110 Mich. App. 693, 313 N.W.2d 191 (1981) 24
Thompson v. *City of Louisville*, 326 U.S. 199, 206 (1960) 13

Turner v. *Department of Employment Security and Board of Review of the Industrial Commission of Utah*, 423 U.S. 44 (1975) 17
United States Department of Agriculture v. *Murry*, 413 U.S. 508 (1973) 17-18, 19
United States v. *Kras*, 409 U.S. 434 (1973) 27
Vachon v. *State of New Hampshire*, 414 U.S. 478 (1974) 13-14
Vlandis v. *Kline*, 412 U.S. 441, 452 (1973) 19
Weber v. *Aetna Casualty & Surety Co.*, 406 U.S. 164, 175 (1972) 11, 28
Weinberger v. *Salfi*, 422 U.S. 749, 772 (1975) 19
Western & Atlantic Railroad Co. v. *Henderson*, 279 U.S. 639 (1929) 17
Williams v. *Oklahoma City*, 395 U.S. 458 (1969) 27, 28
Williamson v. *Lee Optical Co.*, 348 U.S. 483, 488-489 (1955) 28

Constitution

United States Constitution, Fifth Amendment 6
United States Constitution, Fourteenth Amendment 2, 6, 15, 17

Miscellaneous

Annot., 51 A.L.R. 3d 1344, 1349 (1973) 10
S.J.I.2d 25.01 22
S.J.I.2d 25.01 22
S.J.I.2d 25.03 22
S.J.I.2d 25.04 22
S.J.I.2d 25.12 22
S.J.I.2d 25.22 22
S.J.I.2d 25.32 22

Statutes

28 U.S.C. §1257 ..... 7, 8
28 U.S.C. §1257(3) 1
M.C.L.A. 600.2925b(a); M.S.A. 27A.2925(2)(a) 26
M.C.L.A. 600.2945; M.S.A. 27A.2945 ..... 22, 23
M.C.L.A. 600.2946(1); M.S.A. 27A.2946(1) 23
M.C.L.A. 600.2946(2); M.S.A. 27A.2946(2) 23
M.C.L.A. 600.5805(9); M.S.A. 27A.5805(9) 23

Court Rules

M.G.C.R. 1963, 117.2(1) and 117.2(3) 6

Textbook

1 Hirsch & Bailey, *American Law of Products Liability*, §1.41, p. 125 (1974) 10
Restatement of Torts, 2d, §433B(3) 14

To the Honorable Warren E. Burger, Chief Justice of the United States, and to the Honorable Associate Justices of the United States Supreme Court:

Petitioner, E. R. Squibb & Sons, Inc., respectfully prays that a Writ of Certiorari be issued to review the opinion and judgment of the Supreme Court of Michigan entered on February 6, 1984 and March 26, 1984, respectively.

OPINIONS BELOW

The Opinion of the Supreme Court of Michigan is reported at 418 Mich. 311, 343 N.W.2d 164 (1984), and is reproduced in the Appendix annexed to this Petition. (App. A1-A29)

This matter was also reviewed at the intermediate appellate court level by the Michigan Court of Appeals. This latter opinion is reported at 94 Mich. App. 59, 289 N.W.2d 20 (1979) and is also found in the Appendix. (App. A35-A63)

JURISDICTION

The Judgment Order of the Supreme Court of Michigan sought to be reviewed was entered on March 26, 1984; the opinion of the court below was entered on February 6, 1984. A Motion for Rehearing was duly and timely filed on February 24, 1984. On March 26, 1984, the Supreme Court of Michigan denied this Motion for Rehearing. (App. A33) The jurisdiction of the Court is invoked under 28 U.S.C. §1257(3).

CONSTITUTIONAL PROVISIONS INVOLVED

The Fourteenth Amendment to the Constitution of the United States provides in pertinent part:

> "No State . . . shall . . . deprive any person of life, liberty or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

STATEMENT OF THE CASE

1. The court below fashioned a new "DES-unique" theory (App. A20) in this drug products liability case which was ". . . tailored to accommodate the[se] unique facts . . ." against the manufacturers of diethylstilbestrol (DES), dienestrol, and diethylbestrol dipropionate (DSD). (App. A19)

Originally developed in 1938 by C. E. Dodds, a British researcher, in 1938 (App. A5), synthetic estrogens were never patented and were, at first, generically marketed for purposes other than to stabilize pregnancy. (App. A5) Diethylstilbestrol (DES) was first approved for non-pregnancy uses in 1941 by the Food and Drug Administration. (App. A5) In 1947, the drug had begun to be used to prevent complications in pregnancy after the Food and Drug Administration granted permission to market the drug generically. (App. A5-A6) While no ill effects were noted in the pregnant women who took diethylstilbestrol (DES), or dienestrol, or diethylbestrol dipropionate (DSD) to assist in the prevention of miscarriage, their daughters, who were exposed to synthetic estrogens *in utero*, and their spouses claim various personal injuries. (App. A6)

Dr. Dodds never patented the drug, which meant that it could be marketed by anyone. (App. A138) Because many firms were filing separate synthetic estrogen New Drug Applications (App. A176) for non-pregnancy uses (App. A141), Dr. Theodore G. Klumpp, the head of the newly-created Food & Drug Administration, deemed it in the public interest to have all such clinical material pooled. (App. A178) The manufacturers resisted this pooling. (App. A178) Nevertheless, on December 30, 1940, before DES use in pregnancy was considered, the FDA demanded that all companies file joint data. (App. A187) Ultimately, the FDA concluded that DES was safe and effective. (App. A186) About this time, leading independent medical researchers, George and Olive Smith, had also begun to conclude that natural estrogens, and then DES, could assist in the prevention of some pregnant women from miscarrying. (App. A153) By 1947, several different applications had been filed with the FDA to market synthetic estrogens to prevent accidents in pregnancy. Petitioner did so on April 28, 1947. (App. A171) At this time, no "pooling" or "master file" was required by the FDA. Separate data was required. 21 U.S.C. §355(d), 21 C.F.R. §310.3. Between 1947 and 1964, 300 different companies were distributing or manufacturing synthetic estrogens for the prevention of some pregnancy accidents. (App. A113-A119)

In 1971, Dr. Arthur Herbst and others published a paper (found at 284 New Eng. J. Med. 878) which disclosed for the first time a statistical association (*not* a cause and effect relationship) between the use of synthetic estrogens and a form of gynecological cancer, clear cell adenocarcinoma) in a few of the female offspring of pregnant women ingesting the drug. While petitioner denies that the use of its product can or does cause personal injuries of any kind to anyone, it is of consequence

to note that only a very few of the 142 female plaintiffs claim to suffer from cancer; virtually all of the female plaintiffs claim to have benign adenosis, which is the presence of normal columnar cells, glandular tissue, in the vagina rather than the endocervix. For a complete history and discussion of synthetic estrogens, the Court is referred to the Appendix.

Of the one hundred and eighty-three (183) claimants in this case, approximately seventy (70) are able to identify with specificity both the manufacturer and the substance ingested. (App. A24) The roughly one hundred and thirteen (113) plaintiffs who remain can make no such identification. The court below acknowledged that these plaintiffs must be permitted to "circumvent" (App. A7) or to "bypass" (App. A7) the traditional notions of products liability proof in order to succeed against the manufacturers and distributors with joint and several liability. (App. A9, A23) The court below agreed that, generally speaking, the threshold requirement of any products liability action is the identification of the injury-causing product and its manufacturer, which ultimately means that a claimant must produce evidence of a product defect which caused the accident, and thereafter trace that product defect into the hands of the defendant sought to be held liable. (App. A13) Framing the *Abel* rule as "alternative liability", which presupposed that all tortfeasors are before the court, and relying upon *Summers* v. *Tice*, 33 Cal.2d 80, 199 P.2d 1 (1948), the Michigan court adopted that California doctrine but modified it to apply solely to the DES cases. (App. A18-A20) The Michigan Supreme Court did so with serious misgivings, noting the fundamentally distinguishable nature of *Summers* and the DES litigation. (App. A18-A19) Nevertheless, the Michigan court ratified a theory which extended joint and several liability to each of the defendants in a DES case,

even though in many such cases, each of the individual plaintiffs will not be able to prove, or even know, which of the defendants, if any, manufactured or distributed the synthetic estrogen ingested by their mothers. (App. A19)

The "DES-unique" alternative liability doctrine presented in this case eliminates the traditional civil burdens of proof of identifying specifically the tortfeasor who caused each specific harm and of causation in fact (App. A21), if certain prerequisites are met. If all potential tortfeasors are before the court, if all such defendants have distributed or manufactured DES, DSD or dienestrol, if the female plaintiffs' mothers ingested DES, DSD or dienestrol, if such drugs were distributed or manufactured in Michigan, and if these drugs caused the type of injury of which the plaintiffs complain, then it is not necessary for each such plaintiff to prove that each such defendant specifically caused allocable harm. (App. A21-A22) If the defendants sued are unable to exonerate themselves, joint and several liability as to each defendant results. (App. A23)

The approximately seventy (70) plaintiffs who were able to identify the manufacturer or distributor or the substance may bring forth their proofs at trial, and if not able or willing to establish the required identification, these seventy may resort to the alternative liability theory specified by the Michigan Supreme Court. (App. A25)

Acknowledging that "unanticipated jurisprudential procedural and substantive issues" would arise (App. A28), the court below stated, "the fairness of the application at trial of the theory of alternative liability remains to be seen". (App. A28)

2. *Pretrial and Intermediate Appellate Court History.* The background of the cases is as follows. Before

trial, defendants sought in a motion filed on December 23, 1974, to obtain summary judgment against all plaintiffs who were unable to identify the responsible manufacturer or drug ingested. The trial court denied this Motion without prejudice and ordered further discovery taken. After approximately two years of discovery, defendants moved anew for partial summary judgment on the grounds set forth in the Michigan General Court Rules, M.G.C.R. 1963, 117.2(1) and 117.2(3). Finding that the plaintiffs had not stated claims against those defendants which plaintiffs could not identify as responsible or to specify what drug, if any, was involved, the trial judge, on August 25, 1977, granted summary judgment. (App. A7) As to those seventy (70) plaintiffs who were able to identify the manufacturer or distributor or the drug involved, the trial court dismissed all other defendants. (App. A7) On appeal, the Michigan Court of Appeals reversed the granting of the summary judgment, initially finding causes of action under alternative liability and concert of action theories to be viable. (App. A35-A47)

3. *Preservation of the Issues Below.* The issues presented by this Petition were raised and preserved. As indicated above, petitioner, along with all other defendants, filed a Motion for Summary Judgment which the trial court granted. In the defendants' Joint Brief in Support of the Joint Motion for Partial Summary Judgment, at p. 37, petitioner objected to the imposition of industry-wide liability in the face of plaintiffs' inability to prove the specific tort involvement of petitioner on the basis of the Fifth and Fourteenth Amendments to the Constitution of the United States. (App. A65) An argument found in defendants' Joint Reply Brief filed in the trial court on March 22, 1977, pp. 47-51, also at-

tacked the extension of tort liability on the basis of federal due process and equal protection of laws. (App. A66-A71) When the case was appealed to the intermediate Michigan Court of Appeals, Defendants-Appellants' Brief on Appeal, pp. 46, 120-124, registered constitutional objections. (App. A72-A77) In dissent, Court of Appeals Judge Moore (App. A48-A63) reviewed the constitutional questions raised by defendants on appeal, and agreed that the alternative liability doctrine could not constitutionally be permitted. Before the Michigan Supreme Court, Defendants-Appellants' Brief on Appeal, pp. 47-49 (App. A78-A80) articulated the due process and equal protection of the laws issues stated here. After the opinion of the Michigan Supreme Court was announced on February 6, 1984, petitioner filed an extensive, timely Motion for Rehearing, which addressed identical constitutional arguments with reference to the lower court's opinion. (App. A8-A112)

The petition for rehearing was denied by order but without opinion on March 26, 1984. (App. A33-A34)

4. *The Finality of the Judgment.* The state judgment sought to be reviewed here is final within the meaning of 28 U.S.C. §1257 despite the fact that, on the remand contemplated by the decision below, petitioner may conceivably win ultimate vindication on grounds other than those set forth in this petition. The state judgment is final because it denied petitioner its constitutional right to be free from the need to defend at all in the Michigan courts, given that the plaintiffs plainly cannot show that any Squibb product caused the injuries or the damages claimed. Furthermore, the statement of the Michigan Supreme Court in the penultimate paragraph of its opinion (App. A29) that it intends in the future to pass upon the validity of any verdict under the theory advanced by the Michigan court, denies the

rights of petitioner to be free from the heavy financial burden of defending hundreds of such cases when there is indisputably no proof of actual tort causation in the first place. That the Michigan court was uncertain as to whether its "DES-unique" cause of action possessed validity (App. A29) should not serve as a vehicle to evade review. The cases are final since petitioner is compelled to defend them despite the undisputed lack of specific proof against it.

The problem of what constitutes a final judgment under Section 1257 has occasioned difficulty over the years. See *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 476-87 (1975). But the Court has left no doubt whatever that a state judgment is final within the meaning of Section 1257 if in contravention of a federal claim to be free from the need to defend in a state court, notwithstanding the possibility that the defendant might ultimately prevail in proceedings on the merits in such court. Clear holdings to this effect include *Shaffer* v. *Heitner*, 433 U.S. 186, 195 n. 12 (1977) (constitutional objection to exercise of state court jurisdiction founded solely on presence of property within state; if objection is sound "there should be no trial at all"); *American Motorists Insurance Co.* v. *Starnes*, 425 U.S. 637, 642 n. 3 (1976) (constitutional objection to state venue statute as violative of equal protection clause); *Michigan Central Railroad Co.* v. *Mix*, 278 U.S. 492 (1929) (constitutional objection to trial in state court as excessive burden on interstate commerce in violation of Commerce Clause); *Harris* v. *Washington*, 404 U.S. 55, 56 (1971) (state order requiring trial despite claim of double jeopardy); *Local 438 Construction & General Laborers' Union, AFL-CIO* v. *Curry*, 371 U.S. 542 (1963) (trial in state court in contravention of claimed pre-emptive effect of federal labor legislation);

Mercantile National Bank v. *Langdeau*, 371 U.S. 555, 557-58 (1963) (trial in state court in contravention of a claim that federal statute conferred privilege of trial in a different venue).

REASONS FOR ALLOWANCE OF THE WRIT

The Court has rightly afforded review in those cases in which state courts have enforced prejudgment attachment, garnishment, or process, since allowing one private litigant to marshal the majesty of the state to take the property of another before a proving of the underlying cause of action, is an affront to the due process clause. *North Georgia Finishing, Inc.* v. *Di-Chem, Inc.*, 419 U.S. 601 (1975); *Lugar* v. *Edmonson Oil Co.*, 457 U.S. 922 (1982); *Snadiach* v. *Family Finance Corp.*, 395 U.S. 337 (1969); *Fuentes* v. *Shevin*, 407 U.S. 67 (1972). In the case now before the Court, the Supreme Court of Michigan has devised an equally repugnant rule for trial, one which permits an individual products liability claimant to secure the taking of a defendant's property based upon a burden-shifting presumption which nullifies the central concept of all American products liability—indeed, of all civil law: causation. A civil plaintiff must always show a defendant caused the damage in order to recover. It makes no analytical difference that the taking, under *Abel*, follows a trial which is inherently unfair based upon a palpable lack of proof, any more than the *Snadiach* sequestration of assets occurs before a fair trial. In both instances, property is taken without demanding absolutely essential prior proof within the context of a fair trial. Here, the clarion call for review is no less compelling, as it was in the foregoing cases. At stake is the fundamental fairness of the civil legal system, which

hinges upon a fair burden of proof balanced roughly equally between civil litigants.

Because of the ramifications of the *Abel* rule in abolishing the typical civil requirement of showing tort fault before ordering a transfer of property, the case is one which presents federal constitutional issues of such national importance that they should be settled by the Court.

The Michigan Supreme Court opinion itself recognized that the novel approach it took was based upon a legal precedent, *Summers* v. *Tice,* 33 Cal.2d 80, 199 P.2d 1 (1948), which concededly did not fit neatly into the mold. (App. A18) The court below candidly observed, "[h]ere [as opposed to *Summers*], the plaintiffs do not even claim that each of the [16] defendants was negligent toward each of the [183] plaintiffs. Therefore, each of the defendants in this case could not have caused injury to each of the plaintiffs." (App. A19)

Since the advent of the law of American products liability, one thing, and one thing alone, has kept manufacturers, distributors, and even the legal system from becoming inundated with such civil cases. This has been the requirement that products liability claimants prove the existence of a defect in a product, identify the manufacturer of the product and establish the relationship of the claimed injuries to the product defect so proven. See 1 Hirsch & Bailey, *American Law of Products Liability,* §1.41, p. 125 (1974); Annot., 51 A.L.R. 3d 1344, 1349 (1973); see, also, *Piercefield* v. *Remington Arms,* 375 Mich. 85, 98-99, 133 N.W.2d 129 (1965); *Heckel* v. *American Coupling Corp.,* 384 Mich. 19, 21, 22, 179 N.W.2d 381 (1970); *Caldwell* v. *Fox,* 394 Mich. 401, 410, 231 N.W.2d 46, 50 (1975). The basic concept of the American legal system is that legal burdens should bear some

relationship to individual responsibility or wrongdoing. *Weber* v. *Aetna Casualty & Surety Co.*, 406 U.S. 164, 175 (1972).

Petitioner suggests that the root of the requirement that products liability claimants must prove identification and responsibility before the state assists them in taking the property of defendants-manufacturers rests, at bottom, in the due process and equal protection of laws clauses which presuppose such a showing before the transfer of property. Indeed, at least one court has forthrightly rejected alternative liability as such a taking of property, *Namm* v. *Charles E. Frosst & Co., Inc.*, 178 N.J. Super. 19, 427 A.2d 1121, 1128 (1981). California has adopted an equally unacceptable "market share" approach, but in deciding the question, declared identical constitutional arguments "persuasive". *Sindell* v. *Abbott Laboratories*, 26 Cal.3d 588, 603, 163 Cal.Rptr. 132, 607 P.2d 924, *cert. den.* 449 U.S. 912 (1980). The Michigan Court of Appeals' dissent of Judge Moore in this case declined to extend the "collective group liability" doctrine as in violation of constitutional principles. (App. A61)

The concept of products liability without proof of causation is one which extends beyond the mere "toxic torts" relating to Agent Orange, asbestos, DES, pesticides, herbicides, paints, dyes, food additives, et cetera. If Michigan were alone, there would be no reason for alarm, although there still would be reason to act. Unfortunately, tort liability without a prior showing of causal product exposure has enjoyed growing receptivity across the nation. See, for example, *Insurance Co. of North America* v. *Forty-Eight Insulations, Inc.*, 633 F.2d 1212, 1215, fn. (3), 1225 (C.A. 6, 1980), *cert. den.* 454 U.S. 1109 (1981); *Borel* v. *Fibreboard Products*, 493 F.2d 1076, 1094-1096 (C.A. 5, 1973), *cert. den.* 419 U.S. 869 (1974); *Hall* v. *E. I. Dupont*

de Nemours & Co., 345 F.Supp. 353 (D.C. N.Y., 1972); *Sindell* v. *Abbott Laboratories*, 26 Cal.3d 588, 163 Cal.Rptr. 132, 607 P.2d 924, *cert. den.* 449 U.S. 912 (1980); *Bichler* v. *Eli Lilly Co.*, 436 N.Y.S.2d 625 (1981), *aff'd* 436 N.E.2d 182; *Collins* v. *Eli Lilly Co.*, 116 Wis.2d 166, 342 N.W.2d 37 (1984), *certiorari pending*.[1]

Petitioner respectfully submits that it is now time to resolve whether due process and equal protection of the laws sanction the awarding of money damages without a prior showing of causal product involvement, manufacture and defect. To postpone consideration of such nationally important issues not only compels products liability manufacturers unreasonably and unnecessarily to expend substantial legal defense costs, but also arbitrarily requires them to pay judgments on the basis of "industry-wide" liability, amounting to judicial guesswork.

I.

The Abel Rule Establishes Civil Products Liability Without a Prior Showing of Tort Fault and Is a Taking of Petitioner's Property Without Due Process of Law.

The Michigan Supreme Court understood that it was expanding petitioner's tort liability to joint and several status among other manufacturers of synthetic estrogens by the *Abel* rule. (App. A23) It also comprehended that the *Abel* rule could result in petitioner being required to pay damages to claimants it had not actually injured. (App. A19) Given Michigan law relating to joint tortfeasor liability—that any one of the sixteen or more de-

---

1. *Collins* involves DES and substantially similar constitutional issues. A writ of certiorari is also sought before the Court. Contemporaneous with the filing of this petition, petitioner will request consolidation of these two petitions for the sake of judicial economy.

fendants found liable could be called upon to pay the entire judgment *in toto*[2]—the Michigan court did not appear to be concerned that petitioner would be called upon to pay all or a portion of products liability judgments as to which no one could hazard a guess as to their having been justly decided.

The federal constitutional guarantee of due process extends to state action through judicial decisions as well as those taken by the executive or legislative departments of the state. *Brinkerhoff-Farris Trust & Savings Co.* v. *Hill*, 281 U.S. 673, 680 (1930). In its purest form, "due process of law" implies a conformity with natural and inherent principles of justice which forbids the arbitrary taking of another's property. *Holden* v. *Hardy*, 169 U.S. 366 (1898). Certainly, at least, the traditional notions of due process of law are of the essence of fair play, prohibiting government from arbitrary actions and furnishing the matrix of fundamental fairness. *Galvan* v. *Press*, 347 U.S. 522 (1954); *Slochower* v. *Board of Higher Education of New York City*, 350 U.S. 551 (1956); *Lassiter* v. *Dept. of Social Services of Durham County, North Carolina*, 452 U.S. 18 (1981). Any involuntary transfer of property must, in order to be sustained, afford the party prejudiced due process of law, the *sine qua non* for such a taking. *Snadiach* v. *Family Finance Corp.*, 395 U.S. 337 (1969).

The Court has held before that due process of law requires that the state present evidence of an individual's guilt before it is legally empowered to punish him. *Thompson* v. *City of Louisville*, 362 U.S. 199, 206 (1960). See, also, *Vachon* v. *State of New Hampshire*, 414 U.S. 478

---

2. See *Bowerman* v. *Detroit Free Press*, 279 Mich. 480, 489-490, 272 N.W. 876, 880 (1937); *Bishop* v. *Plumb*, 363 Mich. 87, 90, 108 N.W.2d 813, 814(1961).

(1974); *Cole* v. *State of Arkansas*, 333 U.S. 196, 201 (1948); *Harris* v. *United States*, 404 U.S. 1232, 1233 (1971) (Opinion of Douglas, J.); *Johnson* v. *State of Florida*, 385 U.S. 39, 44 (1966).

Playing the statistical averages—that petitioner will sometimes pay tort judgments that are (on a sheerly random chance basis)—fairly or unfairly decided, is a patchwork system designed to work with only a blind eye to proof of actual fault. Since plaintiffs cannot furnish the courts with any identification evidence, under the alternative liability doctrine—"DES-unique"—petitioner, in many such cases, will be equally uncertain. Therefore, the individual respondents will prevail and the state will require that petitioner pay damages without being compelled to prove to the satisfaction of the jury by a civil preponderance that *any* tort defendant present in the courtroom is in fact responsible.

The "fundamentally fair" concept that the plaintiff show tort fault which caused injury on the part of a defendant—or defendants—is rooted in the due process clause. To abolish such fairness by the "DES-unique" vehicle of alternative liability is to exempt alleged DES defendants from due process considerations—the most fundamental being that such defendants be proven to have a causal relationship to a plaintiff's injuries. Under the *Abel* rule, if the state will call upon petitioner to transfer its property to claimants in those cases where *nobody* knows or can prove any causal connection or relationship to a product, then the law of products liability has become an exercise in raw power, suspending the due process clause in favor of the Restatement of Torts, 2d, §433B(3), "DES-modified".

II.

The Abel Rule Creates an Irrebutable Presumption Which Destroys the "Roughly Equal" Allocation of Burden of Proof in Civil Cases and Which Laterally Transfers the Burden of Products Liability Proof Upon an Irrational Premise Which Violates Petitioner's Rights to Due Process.

A.

The procedural effect of the *Abel* rule is to create a mandatory presumption of injury causation as to each of the products liability defendants based upon the additional factual premise that if "all" tortfeasors are before the court, then therefore, one unidentified member must have caused each plaintiff's injury.

In creating such a rule, which shifts the ordinary burden of proof of product and identification to the manufacturers to disprove, the Michigan court observed that ". . . defendant's access to evidence of causation is not a relevant factor", and that, ". . . the defendant's access to evidence as a controlling consideration has been criticized". (App. A22)

First of all, the Michigan court's creation of a burden-shifting doctrine which focuses only on the interest of the claimants to recover damages, but not upon manufacturers or distributors to defend themselves—or even that such a consideration should be "criticized"—moves petitioner to reply with objections that focus upon procedural guarantees secured by the due process clause of the Fourteenth Amendment of the Constitution of the United States. In *Heiner* v. *Donnon,* 285 U.S. 312, 329 (1932), the Court held:

> "The Court has held more than once that a statute creating a presumption which operates to deny a fair

opportunity to rebut it violates the due process clause of the Fourteenth Amendment."

In those cases where both the plaintiffs and petitioner cannot prove the identity of the responsible manufacturer, under the *Abel* rule, petitioner will fail in its defense and will be unable to rebut the burden of proof shifted to it. The guarantees of due process in civil procedure requires that petitioner be given an opportunity to present every available defense. *Lindsey* v. *Normet,* 405 U.S. 56, 67 (1972); *American Surety Co.* v. *Baldwin,* 287 U.S. 156, 158 (1932). See, also, *Nickey* v. *State of Mississippi,* 292 U.S. 393, 396 (1934). Such an opportunity must be reasonably adequate to meet the task. Due process precludes a presumption which is entirely arbitrary, which creates an invidious discrimination or which deprives petitioner of a reasonable opportunity to present the pertinent facts in its defense. *Bondini Petroleum Co.* v. *Superior Court, Los Angeles County, California,* 284 U.S. 8, 19 (1931). If plaintiffs cannot tell which of the manufacturers, if any, are causally responsible for the tort, in many cases, petitioner will also fail to specify the responsible manufacturer. According to the Michigan court, the inability of defendants to present evidence in their own behalf is a cipher to ignore, not a controlling consideration, something to be "criticized". (App. A22)

Furthermore, the Michigan court noted, ". . . the *raison d'etre* of alternative liability is to shift an onerous proof requirement where to do otherwise would leave an innocent plaintiff remediless". (App. A24) The Court has previously stated in *Rees* v. *Watertown,* 86 U.S. (19 Wall.) 107, 122 (1874), that, "[a] Court of equity cannot, by avowing that there is a right but no remedy known to the law, create a remedy in violation of law or even without the authority of law". Petitioner believes that

the Michigan Supreme Court has attempted to create a substantive remedy for the plaintiffs in this case by, practically speaking, stripping away traditional products liability defenses from petitioner, which leaves petitioner procedurally rudderless. When a state tort case involves a presumption which is "rebuttable" on the surface but which is, in practice, conclusive or permanent, the Court has struck down the use of it as a Fourteenth Amendment violation of due process insofar as it deprives the defendant of a fair opportunity to repel it. *Western & Atlantic Railroad Co.* v. *Henderson,* 279 U.S. 639 (1929); see, also, *Alabama Great Southern Railroad Co.* v. *Allied Chemical Corp.,* 501 F.2d 94, 99, 100 (C.A. 5, 1974), *reh. den.* 509 F.2d 539 (1974).

B.

Secondly, such mandatory presumptions—that (1) the tortfeasor who caused each plaintiff's injury is actually before the court; and (2) therefore, the lower court is justified in shifting the presumed fact of causation over to defendants to disprove *inter se*—are only to be sustained as valid under fundamental concepts of due process if there is a more-likely-than-not rational connection between the facts proven and the matters to be presumed. *Leary* v. *United States,* 395 U.S. 6, 36 (1969); *Mobile, Jackson & Kansas City Railroad Co.* v. *Turnipseed,* 219 U.S. 35, 43 (1910).

In the past, the Court has invalidated presumptions which arbitrarily deprived litigants of an individualized determination and a fair ability to defend themselves from an assumed fact. *Turner* v. *Department of Employment Security and Board of Review of the Industrial Commission of Utah,* 423 U.S. 44 (1975); *Stanley* v. *State of Illinois,* 405 U.S. 645 (1972); *Cleveland Board of Education* v. *LaFleur,* 414 U.S. 632 (1974); *United States De-*

partment of Agriculture v. *Murry,* 413 U.S. 508 (1973); *Bell* v. *Burson,* 402 U.S. 535 (1971); *Heiner* v. *Donnon,* 285 U.S. 312 (1932). Since petitioner can be held liable under the *Abel* rule for the entire amount of damages without any prior showing of Squibb product involvement, in those many cases where neither party knows who was the responsible manufacturer or distributor, the burden-shifting presumption becomes virtually irrebuttable. Petitioner suffers the detriment.

Also of cogent force is the point that the bedrock factual basis of the *Abel* rule, i.e., that "all" tortfeasors are before the Court, is, for two reasons, demonstrably erroneous.

First, it is also apparent from the opinion of the Michigan court itself that fourteen of the original thirty synthetic estrogen manufacturers have already been dismissed. (App. A8) The trial court record supports that there are roughly three hundred manufacturers and distributors of synthetic estrogens in America from 1950 to 1964. (App. A113-A119) There now exists a real and distinct mathematical probability that the actual, but unidentified, tortfeasor will never be before the courts. With sixteen defendants present, fourteen having escaped and three hundred possibly responsible but not before the court, the use of the *Abel* mandatory presumption becomes both false and irrational. Secondly, the trial court record shows that the mandatory presumption is irrational because the *Abel* presumption hinges, in part, on distribution or manufacture solely based in Michigan, and indisputably, some of the plaintiffs' mothers purchased the drug in several states other than Michigan. (App. A120-A127)

Since the mandatory *Abel* presumptions from these perspectives are "not necessarily or universally true in fact", the procedural operation of the presumptions, if vir-

tually permanent and conclusive, do not survive the test of due process. See *Vlandis* v. *Kline,* 412 U.S. 441, 452 (1973).

While it is certainly true that a presumption may not be a deprivation of due process if there is a meaningful and adequate opportunity to rebut or disprove the facts so presumed, *Weinberger* v. *Salfi,* 422 U.S. 749, 772 (1975), the Courts considering the constitutional question have had great difficulty when the presumption is permanent and irrebuttable, either by operation of law or *de facto. Vlandis* v. *Kline,* 412 U.S. 441, 446 (1973); *Cleveland Board of Education* v. *LaFleur,* 414 U.S. 632 (1974); *Stanley* v. *Illinois,* 405 U.S. 645 (1972); *United States Department of Agriculture* v. *Murry,* 413 U.S. 508 (1973); *Bell* v. *Burson,* 402 U.S. 535 (1971); *Carrington* v. *Rash,* 380 U.S. 89 (1965). The due process clause demands a more individualized determination; one that is not formed on rules which are "neither necessarily nor universally true". *LaFleur,* at 645, 646. Petitioner has been denied this individualized determination.

C.

To shift the burden of proof of causation to each of the defendants is, in effect, to create a mandatory presumption of tort causation. A mandatory presumption is a "troublesome evidentiary device". *County Court of Ulster County* v. *Allen,* 442 U.S. 140, 157 (1979). Such a presumption ". . . tells the trier that he, she or they *must* find the elemental fact upon proof of the basic fact, unless the defendant has come forward with some evidence to rebut the presumed connection between the two facts". *Allen,* at 157. The Michigan Supreme Court thus created a mandatory presumption of causation (and therefore liability) by, in effect, requiring plaintiffs to prove only the four elements listed at App. A21-A22.

Due process requires a proper standard of proof and an appropriate placement of the burden of proof. In *Matthews* v. *Eldridge,* 424 U.S. 319 (1976), the Court identified three factors, a consideration of which assists in the determination of whether a particular standard of proof satisfies due process. Those three factors are as follows: first, the private interests affected by the proceedings; secondly, the risk of error created by the state's chosen procedure; and thirdly, the countervailing governmental interest support the use of the challenged procedure. The overall consideration of these factors was summarized by the Court in *Addington* v. *Texas,* 441 U.S. 418, 423 (1979), when it articulated the interplay between a party's due process rights in light of the burden of proof imposed upon that party:

> "The function of a standard of proof, as that concept is embodied in the due process clause and in the realm of factfinding, is to 'instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.' [Citation omitted.] The standard serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.
>
> "Generally speaking, the evolution of this area of the law has produced across a continuum three standards or levels of proof for different types of cases. At the one end of the spectrum is the typical civil case involving the monetary dispute between parties. Since society has a minimal concern with the outcome of such private suits, plaintiff's burden of proof is a mere preponderance of the evidence. The litigants thus share the risk of error in roughly equal fashion."

The *Addington* Court's instruction that the function of the burden of proof is to minimize the risk of erroneous decisions and to allocate the risk of error equally between the litigants highlights the impropriety of the Michigan court's determination that, notwithstanding the fact that the instant plaintiffs do not have access to the sources of proof, petitioner, who suffers from the same impediment, nevertheless is in a better position to assume the burden of proof. In other words, the Michigan court's placement of the burden of proof on petitioner falls short of meeting the demands of due process, because it imposes a burden upon petitioner that cannot be met, and thereby erects an unreasonable barrier to the goal of an equal sharing of the risk of error reflected by *Addington*.

The *Addington* decision was of particular concern to the Court in its latter opinion in *Santosky* v. *Kramer*, 455 U.S. 745 (1982). That Court, in following the *Addington* decision, emphasized the importance of due process principles in the articulation and placement of the burden of proof in a given case:

> "*Addington* teaches that, in any given proceeding, the minimum standard of proof tolerated by the due process requirement reflects not only the weight of the private and public interests affected, but also a societal judgment about how the risk of error should be distributed between the litigants.
>
> "Thus, while private parties may be interested intensely in a civil dispute over money damages, application of a 'preponderance of the evidence' standard indicates both society's 'minimal concern with the outcome,' and a conclusion that the litigants should 'share the risk of error in roughly equal fashion.'" 455 U.S. 745, 755.

As explained by the *Santosky* Court, the standard of proof in a criminal action is designed to exclude as nearly as possible the likelihood of an erroneous judgment. Consequently, the stringency of a "beyond a reasonable doubt" standard bespeaks the weight and gravity of the private interest affected, society's interest in avoiding erroneous convictions, and a judgment that those interests together require that society impose almost the entire risk of error on itself. To the contrary, the nature of a civil case requires, as between those most interested in its outcome, those being the parties to the action, that the risk of error be equally distributed.

Accepting that the three *Eldridge* factors compelled different and distinct standards of proof in criminal and civil actions, the *Santosky* Court cautioned against development of different standards of proof framed to meet particular intricacies of each case:

> "But this Court has never approved case-by-case determination of the proper standard of proof for a given proceeding. Standards of proof, like other 'procedural due process rules[,] are shaped by the risk of error inherent in the truth-finding process as applied to the generality of cases not the rare exceptions.' *Matthews* v. *Eldridge*, 424 U.S., at 344. (Emphasis supplied.) Since the litigants and the factfinder must know at the outset of a given proceeding how the risk of error will be allocated, the standard of proof necessarily must be calibrated in advance. Retrospective case-by-case review cannot preserve fundamental fairness when a class of proceedings is governed by a constitutionally defective evidentiary standard." 455 U.S. 745, 757.

The lower court's decision contravenes the due process notion that standards of proof are to be developed by

a consideration of the general nature of cases and not on a case-by-case basis. By acceptance of the unique and peculiar standard of proof for DES-type cases, the lower court has upset the equally balanced "risk of error" factor by placing upon defendants an unjustified burden of accepting all chance of error. As the lower court has conceded, App. A19, and as has been understood in numerous other DES-type cases throughout this country, *Sindell*, at 603, there exists in each case the very real possibility that the true wrongdoer has not been named a party to the suit and/or that the named defendants will have to pay damages for injuries not caused by their products. To the extent that a procedural burden-shifting presumption commands such a result, petitioner believes due process is violated.

III.

The Abel Rule Strips Away Numerous Valuable Substantive and Procedural Rights Available to All Other Michigan Products Liability Defendants, and in Doing So, Deprives Petitioner of Equal Protection of the Laws.

Three is no doubt but that the Michigan court intended to discriminate against a manufacturer or distributor of synthetic estrogens by establishing a hitherto unknown cause of action which is ". . . modified, however, to accommodate the unique facts of this unusual litigation". (App. A18) To do so, the Court was willing to take a concededly inapposite precedent, *Summers* v. *Tice*, 33 Cal.2d 80, 199 P.2d 1 (1948), which was noted to be "distinctly different", but which the court would tailor ". . . to accommodate the unique facts of this case . . . ." (App. A19) The cause of action so authorized is both "DES-unique" and "DES-modified". (App. A20-A21) The "brand name"

classification is so sharply drawn in this case that the court below had to carve it out with its own "DES-unique" sobriquet.

What is the hallmark of this *sui generis* legal doctrine? Under the *Abel* rule, plaintiffs need not show that each of the defendants sought to be held liable have not caused the plaintiffs' injuries, or, indeed, even that they have used or been exposed to the products in question; thereafter, defendants must prove lack of causation or otherwise be subjected to joint and several liability. (App. A23)

What rights do other Michigan products liability defendants similarly situated have which, by the lower court's opinion, are to be denied to petitioner? First of all, the requirements that a products liability plaintiff prove and identify manufacturer, defect, causation and damages are eliminated. This fundamental point of law is established in the common law. See Page 10 of this petition. The burden of plaintiffs' proof is additionally codified in otherwise applicable Michigan jury instructions. See S.J.I.2d 25.32. See, also, S.J.I.2d 25.01, 25.02, 25.03, 25.04, 25.12, 25.22. Under S.J.I.2d 25.32, plaintiffs in the instant cases would otherwise be required to prove on an individual basis (1) that petitioner manufactured the product which created an unreasonable risk of harm; (2) that this harm was foreseeable *at the time the product was manufactured;* (3) that petitioner failed to exercise reasonable care in manufacturing the product so as to eliminate the risk of harm; (4) that the plaintiff was injured as a result of petitioner's alleged negligence, which must be found to have been causally related. The burden of proof is also statutorily recapitulated under M.C.L.A. 600.2945; M.S.A. 27A.2945, since this statute extends to *any* legal or equitable theory brought for personal injuries *caused by or resulting*

from the manufacture of a product.[3] Furthermore, whatever industry standards exist are statutorily admitted into evidence for the benefit of manufacturers; such standards relate to "the time the product was sold or delivered by the defendant to the initial purchaser or user". M.C.L.A. 600.2946(1) and (2); M.S.A.27A.2946(1) and (2).

Furthermore, all other manufacturers are entitled to the benefit of a statute, M.C.L.A. 600.5805(9); M.S.A. 27A.5805(9), which states, in pertinent part, as follows:

> "[I]n the case of a product which has been in use for not less than 10 years, the plaintiff, in proving a prima facie case, shall be required to do so without benefit of any presumption."

Passed as a part of Products Liability Reform legislation along with M.C.L.A. 600.2945, the statute clearly operates in DES cases to eliminate virtually any evidentiary presumption and, like *In Re Certified Questions, Karl* v. *Bryant Air Conditioning Co.*, 416 Mich. 558, 331 N.W.2d 456 (1982), the statute is to be retroactively applied to all cases, including, specifically, DES cases. *Keil* v. *Eli Lilly Co.*, 490 F.Supp. 479 (D.C. Mich., 1980). Since alternative liability as a doctrine is a mandatory presumption which shifts the burden of proof, unlike all other manufacturers with products older than ten years substantially similarly situated, the DES defendants do not obtain the benefit of this important statute.

Moreover, the impact of the *Abel* rule may greatly prejudice the rights of the petitioner among the other de-

---

3. The statute is, of course, remedial and, under Michigan law, is retroactively applied to any and all pending products liability cases, including DES. See *In Re Certified Questions, Karl* v. *Bryant Air Conditioning Co.*, 416 Mich. 558, 331 N.W.2d 456 (1982); *Keil* v. *Eli Lilly Co.*, 490 F.Supp. 479 (D.C. Mich., 1980).

fendants pertinent to Michigan indemnity and contribution rights. Without passing on the merits of such arguments, petitioner protests that it will be treated differently than all other tort defendants similarly situated.

Consider first the law of common law indemnity between defendants in Michigan. At Michigan law, the mere allegation of active tort fault by the primary plaintiff is sufficient to destroy such rights. See *Minster Machine Co.* v. *Diamond Stamping Co.*, 72 Mich. App. 58, 248 N.W. 2d 676 (1976); *Diekevers* v. *SCM Corp.*, 73 Mich. App. 78, 250 N.W.2d 548 (1976); *Duhame* v. *Kaiser Engineering of Michigan, Inc.*, 102 Mich. App. 68, 300 N.W.2d 737 (1980); *Swindlehurst* v. *Resistance Welder Corp.*, 110 Mich App. 693, 313 N.W.2d 191 (1981); *Ingram* v. *Interstate Motor Freight Systems, Inc.*, 115 Mich. App. 559, 321 N.W.2d 731 (1982). Petitioner expects that indemnity cross-defendants may argue that mere imposition of alternative liability is sufficiently active tort fault to defeat common law indemnity. Just as importantly, since each one of the defendants who are held liable to each of the plaintiffs under alternative liability will have no idea whether it—or another defendant—is actually the defendant who is responsible, the ultimate conclusion may be argued to be that such indemnity does not factually or legally exist in such cases.

Moreover, Michigan law for all other tort defendants in the same or similar circumstances holds for a complete allocation of tort fault spread among the defendants (but not as against plaintiff), contribution liability existing for such tortfeasors distributed in accord with their relative degrees of fault. M.C.L.A. 600.2925b(a); M.S.A. 27A.-2925(2) (a) states:

> "In determining the pro rata shares of tortfeasors in the entire liability as between themselves only and

without affecting the rights of the injured party to a joint and several judgment . . . (a) Their relative degrees of tort fault shall be considered."

If there are sixteen or two hundred or three hundred defendants ultimately found liable under alternative liability, upon later contribution, assuming perfect collectibility, each defendant will bear exactly 1/16th or 1/200th or 1/300th of liability. Such a ruling deprives petitioner of its right, for contribution purposes, of being judged comparatively "guilty" or "innocent" along the lines of its own proven tort fault—or lack of it, unlike the legislated protection granted to any other civil defendant.

To petitioner, there is no reasonable basis to the classifications and distinctions made against the DES defendants. The ruling of the lower court constitutes an invidious discrimination, an arbitrary stab at justice which strips petitioner of numerous substantive, procedural, and legal safeguards by fixing damages by random chance.

The lower court suggested, at App. A17, that the purpose of tort law ". . . is to compensate injured persons . . . ." If so, the alternative liability doctrine *is* rationally related to the object or purpose stated, but such a holding itself shows the basic inequality of the *Abel* rule. The purpose of the law of tort is *not* to provide plaintiffs with compensation, but to give a forum of equally fair consideration to claims *and* defenses. Equal protection of law, as a constitutional guarantee, demands that *all* tort plaintiffs and *all* tort defendants be given the same equal chance to prove *or* disprove claims, not to assure that one side always emerges victorious. If rationality is the applicable equal protection test, *Dandridge* v. *Williams,* 397 U.S. 471, 487 (1969); *Ortwein v. Schwab,* 410 U.S. 656 (1973); *United States* v. *Kras,* 409 U.S. 434 (1973); *Williams* v. *Oklahoma City,* 395 U.S. 458 (1969); *Lindsey* v.

Normet, 405 U.S. 56 (1972), the inquiry is whether the "DES" alternative liability doctrine is rationally related to securing a fair trial for all tort litigants. Petitioner respectfully submits that the *Abel* rule is not rationally consonant with providing a fundamentally fair forum for all civil litigants in tort, but rather reflects the lower court's determination to secure a recovery for the DES claimants even if the civil burden of proof must be "circumvented" or "bypassed" to achieve it. The discrimination against petitioner is invidious. *Williamson* v. *Lee Optical Co.,* 348 U.S. 483, 488-489 (1955); *Ferguson* v. *Skupra,* 372 U.S. 726, 732 (1963); *City of New Orleans* v. *Dukes,* 427 U.S. 297, 304 (1976); *Levy* v. *Louisiana,* 391 U.S. 68 (1968).

In the past, the Court has overruled arbitrary, invidiously discriminatory distinctions between civil litigants whenever the state has been unable to show a reasonable relationship to any valid state objective to sustain the uneven treatment. *Lindsey* v. *Normet,* 405 U.S. 56, 76, 77 (1972). See, also, *Levy* v. *Louisiana,* 391 U.S. 68 (1968); *Glona* v. *American Guarantee & Liability Ins. Co.,* 391 U.S. 73 (1968); *Weber* v. *Aetna Casualty & Surety Co.,* 406 U.S. 164 (1972). And see a similar rule in criminal cases, *Williams* v. *Oklahoma City,* 395 U.S. 458 (1969); *Griffin* v. *State of Illinois,* 351 U.S. 12 (1956); *Douglas* v. *State of California,* 372 U.S. 353 (1963); *Rinaldi* v. *Yaeger,* 384 U.S. 305, 310-311 (1966).

Nor is it any answer to any of this to say that because this is the construction of state products liability law, the action of the court below is inviolate. Since court rulings do furnish the basis of "state action", petitioner is entitled to equal protection of law even if the deprivation is occasioned by a ruling of the state court. *Levy* v. *Louisiana,* 391 U.S. 68 (1968); *Barrows* v. *Jackson,* 346 U.S. 249 (1953); *Eskridge* v. *State of Washington,* 357 U.S.

214 (1958); *Draper* v. *State of Washington*, 372 U.S. 487 (1963).

By wresting from petitioner the substantive, procedural, and legal safeguards available to all other manufacturers or products liability defendants, but not to petitioner, the lower court has arbitrarily, harshly, and punitorily carved out an irrationally, invidiously discriminatory rule for DES manufacturers and distributors. By emphasizing repeatedly that the doctrine has been "tailored" in a "DES-unique" way, the Michigan court has crossed the line into an unconstitutional classification. The advancing law of tort is required to stop at the border of the equal protection clause.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that this petition for a writ of certiorari to the Supreme Court of Michigan should be granted.

Respectfully submitted,

PLUNKETT, COONEY, RUTT, WATTERS,
STANCZYK & PEDERSEN, P.C.
By: JOHN P. JACOBS (Counsel of Record)
900 Marquette Building
Detroit, Michigan 48226
Phone: (313) 965-3900
Attorney for Petitioner, E. R. Squibb & Sons, Inc.

HAIGHT, DICKSON, BROWN & BONESTEEL
2800 Twenty-Eighth Street
Santa Monica, California 90404-0132
Phone: (213) 450-6001

DATED: June 19, 1984

APPENDIX

A. Opinion of the Supreme Court of Michigan, dated February 6, 1984

DATE: Where possible, a syllabus (headnote) such as this will be released at the time the opinion is released. This syllabus is *not* a part of the opinion of the Court but has been written by the Reporter of Decisions as a summary of the case for the convenience of the readers. See *United States* v *Detroit Lumber Co*, 200 US 321, 337; 26 S Ct 282; 50 L Ed 499 (1906).

ABEL v ELI LILLY AND COMPANY

Docket No. 64712. Argued March 8, 1983 (Calendar No. 15).—Decided February 6, 1984.

Gail Abel and certain other women who were exposed *in utero* to synthetic estrogen drugs and some of their husbands brought a products liability action in the Wayne Circuit Court against Eli Lilly and Company and other manufacturers of synthetic estrogen products (specifically, diethylstilbestrol, diethylstilbestrol dipropionate, and dienestrol) distributed in Michigan between 1947 and 1964, alleging injuries resulting from the exposure and joint and several liability because of the negligent manufacture and promotion of the drugs despite research which indicated that they were likely to cause cancer, and concert of action with respect to all the manufacturers. Some of the plaintiffs were unable to identify the specific manufacturer of the product which injured them and asserted alternative liability. The Wayne Circuit Court, Thomas Roumell, J., granted the defendants' motion for partial summary judgment against those plaintiffs who could not identify the manufacturers of the drugs re-

sponsible for their injuries and dismissed all defendants not specifically identified as being liable by the remaining plaintiffs. The Court of Appeals, R. M. Maher, P.J., and Bronson, J. (Moore, J., dissenting), reversed, finding that the plaintiffs had made sufficient allegations to support the theories of alternative liability and concert of action (Docket No. 77-3421). The defendants appeal.

In an opinion by Chief Justice Williams, joined by Justices Kavanagh, Levin, Ryan, Brickley, and Cavanagh, the Supreme Court *held*:

The plaintiffs' allegations are sufficient to support theories of alternative liability and concert of action and to withstand a motion for summary judgment for failure to state a claim upon which relief can be granted.

1. A motion for summary judgment for failure to state a claim upon which relief can be granted seeks to test the genuineness of a claim or defense by challenging the legal adequacy of the pleadings. The standard to be applied in considering such motions is whether the plaintiff's claim, on the pleadings, is so clearly unenforceable as a matter of law that no factual development can possibly justify a right of recovery. The trial court does not act as a factfinder or attempt to probe the parties' ability to prove their allegations, but accepts as true all well-pleaded facts.

2. The threshold requirement in a products liability action is identification of the product which caused the injury and of its manufacturer. A plaintiff must show a defect which caused injury and trace the defect to the defendant. An exception to this requirement obtains where there is more than one defendant and all defendants acted tortiously, but only

one caused the plaintiff's injury. In such instances, a cause of action may be stated under the doctrine of alternative liability which shifts the burden on causation in fact to the defendants once an innocent plaintiff demonstrates that all the defendants acted tortiously, but only one unidentifiable defendant caused the plaintiff's injury. If a defendant cannot meet the burden, it may be found jointly or severally liable. The exception prevents the injustice of allowing proved wrongdoers to escape liability for an injury inflicted upon an innocent plaintiff merely because the nature of their conduct and the resulting harm has made it difficult or impossible to prove which has caused the harm. To avail themselves of the eased burden of proof under the exception in a case in which each defendant could not have caused each plaintiff's injury, plaintiffs must show that all the defendants have acted tortiously, that they have been harmed by the conduct of one of the defendants, *i.e.*, bring before the court all actors who may have caused the injury in fact, and that, through no fault of their own, they are unable to identify the actor who caused the injury. The plaintiff must make a *genuine attempt* to locate and identify the tortfeasor responsible for the individual injury. The *genuineness of the attempt must be determined by the trial court,* applying a standard of due diligence. In this case, the plaintiffs must prove that all of the defendants distributed or manufactured one or more of the three drugs involved, that the mothers of the female plaintiffs ingested one of the drugs at issue and not merely *a* synthetic estrogen, that the drug ingested was manufactured or distributed in Michigan, and that the three drugs at issue each caused the type of injury complained of. Some of the plaintiffs allege that they are unable to identify the manufacturer of the product which harmed them through

no fault of their own because of the absence of pharmacy records and the defendants' use of a generic marketing scheme, The allegations are sufficient to withstand a motion for summary judgment for failure to state a claim upon which relief can be granted. The remaining plaintiffs may offer proofs to establish which manufacturers are liable. If they are unable to identify the manufacturers, they may pursue the alternate liability theory.

3. Where it can be established that several defendants acted tortiously pursuant to a common design and that their actions resulted in injury to a plaintiff, all the defendants may be held liable for the results. The concert of action doctrine creates a legal fiction that all who acted tortiously are to be found to have caused the injury in fact, although only one may have caused the actual injury. A plaintiff need not be unable to identify the defendant who caused his injury; rather that defendant is usually identified, but the identification does not preclude the liability of all defendants who acted in concert. In order to withstand a motion for summary judgment for failure to state a claim upon which relief can be granted where concert of action is alleged, a plaintiff need only allege that the defendants were jointly engaged in tortious activity and that as a result of it the plaintiff was harmed. In this case, the plaintiffs alleged that the defendants acted together in negligently manufacturing and promoting drugs which were ineffective and dangerous, inadequately tested, and lacked sufficient warnings. Plaintiffs who alleged injury by a specific manufacturer are not precluded from bringing this cause of action.

Affirmed.

94 Mich App 59; 289 NW2d 20 (1979) affirmed.

(Filed February 6, 1984)

15/March 1983

STATE OF MICHIGAN
SUPREME COURT

No. 64712

GAIL ABEL, ET AL.,
Plaintiffs-Appellees,

v

ELI LILLY AND COMPANY, ET AL.,
Defendants-Appellants.

BEFORE THE ENTIRE BENCH (except Boyle, J.).

WILLIAMS, C.J.

This case is but one of many filed in state and federal courts by daughters of women who had taken DES during pregnancy and their spouses against the manufacturers of synthetic estrogen products.

Very briefly, synthesis of estrogen was first reported by C. E. Dodds, a British researcher, in 1938. Dr. Dodds never patented the drug, known as diethylstilbestrol or DES, thus allowing any manufacturer to develop the drug who chose to do so. The Food and Drug Administration first granted several companies' requests to market DES for non-pregnancy uses in 1941. In 1947, several companies filed supplemental requests to market DES to prevent complications in pregnancy. The FDA granted permission to market the drug for pregnancy uses the same

year, and the drug was thereafter generically marketed[1] for pregnancy uses.

In 1971, Dr. Herbst reported a statistical association between the use of DES by pregnant women and cancer and other cellular abnormalities in the reproductive systems of their children.[2] As a result, the FDA banned the marketing of DES for use by pregnant women. It is the women who were exposed *in utero* to DES and their spouses who now seek to hold the drug manufacturers liable for their injuries in cases filed throughout the country.

---

1. An individual drug product acquires various names.

First, there is the chemical name which attempts to spell out the structural makeup of the drug. Next comes the generic name which may or may not represent an abbreviation of the more complex chemical name. Ordinarily a drug has one generic name, but there are cases where two or three are employed. Finally a drug may acquire multiple trade names used by the various companies engaged in the promotion of the product.

In this case, diethylstilbestrol (or DES), dienestrol, and diethylstilbestrol dipropionate (DSD) are the generic names of the products. Di-erone, for example, was a Kremers-Urban trade name for dienestrol.

Generic drugs are usually marketed at lower prices because their manufacturers avoid the research and development costs normally associated with the introduction of an original product. Comment, *Products Liability for Prescription Drugs*, 23 Syracuse L Rev 887 (1972); *United States* v *Generix Drug Corp*, ... US .....; 103 S Ct 1298; 75 L Ed 2d 198 (1983).

According to defendant's responses to interrogatories, several defendants, for example, Cole Pharmacal Co., Rexall Drug Co., Korer, Inc., Tutag & Co., and Vale Chemical Co. used no trade name at all. Plaintiffs' First Set of Interrogatories to Defendants, Question 2.

2. The link between DES and cancer was discovered through the appearance of a rare form of cancer. Researchers took detailed histories of the women who developed the cancer, including information on maternal ingestion of drugs. From this data, the statistical association was derived. Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L Rev 963, 964, fn 5.

Since the cancer and cellular abnormalities did not develop in the users of the estrogen products, but rather in their offspring, a significant time delay occurred between the ingestion of the drug and the injury which it allegedly caused.

Although each case presents its own factual nuances, one common problem continually reappears: many of the plaintiffs are simply unable to identify the manufacturer of the estrogen product to which they were exposed. The plaintiffs therefore seek some way to circumvent the traditional tort element of causation in fact.

In order to bypass the identification requirement, plaintiffs assert that defendants (who are purportedly all the manufacturers of synthetic estrogens for pregnancy use in Michigan) are jointly and severally liable. Several theories have been advanced to justify this joint liability including alternative liability, concert of action, and what is referred to as "collective" or "industry-wide" liability.

Defendants jointly sought partial summary judgment pursuant to GCR 1963, 117.2(1) against all plaintiffs who were unable to identify the manufacturer of the prescription drug allegedly responsible for their injuries (Motion, 12/23/74, Def App, 41a). The trial judge denied this motion, without prejudice, and ordered further discovery on "the alleged joint or enterprise liability and conspiracy of all defendants" (Order, 3/10/75, Def App, 49a).

After approximately two years of discovery, the defendants again moved jointly for partial summary judgment on the basis of GCR 1963, 117.2(1) and (3). Finding that the plaintiffs had indeed failed to state a cause of action, the trial judge granted summary judgment in favor of defendants and against those plaintiffs who were unable to identify the manufacturer of the drug which allegedly caused their injury. Also, with regard to those plaintiffs able to identify the manufacturer, the court dismissed all other defendants (Order, 8/25/77, Def App, 346a).

On appeal, the Court of Appeals reversed the summary judgment, finding that the plaintiffs had made sufficient al-

legations to support the alternative liability and concert of action theories. *Abel* v *Eli Lilly & Co*, 94 Mich App 59, 77; 289 NW2d 20 (1979). The Court of Appeals reviewed only the defendants' GCR 1963, 117.2(1) claims (failure to state a cause of action); the GCR 1963, 117.2(3) issues (no genuine issue of material fact) were not addressed.

We are called upon today to review the correctness of these rulings. We hold that the plaintiffs have made sufficient allegations to support both the concert of action and alternative liability causes of action.

Pleadings

The female plaintiffs in this case allege that they are daughters whose mothers when pregnant with each took a synthetic estrogen product upon their doctor's advice in order to prevent miscarriage. The remaining plaintiffs are spouses of the daughters.[3]

The complaint alleges that as a result of prenatal exposure to these drugs, the plaintiffs are now suffering from cancerous or pre-cancerous lesions of the vagina.

According to the complaint, the defendant drug companies[4] actively promoted and sold these drug preparations to the medical community, representing that the drugs were safe and effective for use by pregnant women in the prevention of miscarriage. As a result of these representations the drugs were administered to pregnant women during a time period from 1947 to 1964.

---

3. Initially, 16 women and two spouses were named in the complaint. Amendments adding plaintiffs were allowed until May, 1976 (Order, 5/3/76, Defendants' Appendix, 230a). The complaint now includes 184 plaintiffs. (Only 182 of these plaintiffs have chosen to appeal.)

4. Originally, 30 corporations were named as defendants. Several summary judgments were granted dismissing individual defendants. The complaint now names 16 companies as defendants.

Plaintiffs maintain that the defendants knew or should have known that the drugs which they marketed were derived from stilbene, a known cancer-causing agent, and that scientific investigators had recommended against medical use of stilbene derivatives because of possible cancer risks. The complaint also contends that these synthetic estrogen drugs are ineffective in preventing miscarriage.

Plaintiffs' initial complaint stated that all the plaintiffs' mothers had ingested one of seven synthetic estrogens. This number has since been reduced to three: diethylstilbestrol (DES), dienestrol, and diethylstilbestrol dipropionate (DSD).

The complaint sounds in negligence, breach of express and implied warranty, fraud and deceit, strict liability, and conspiracy.[5] The plaintiffs seek to impose joint and several liability upon all the defendants.

Some plaintiffs have specifically named the product to which they were exposed *in utero* and its manufacturer. Other plaintiffs acknowledge that they are unable to identify the specific estrogen product and that they are unable to identify the manufacturer that produced or distributed the product. They allege that good-faith efforts have been made to determine the specific product and manufacturer. However, they cite Michigan law, MCL 338.1118(1); MSA 14.757(18)(1), which required the preservation of the prescription records of pharmacies for only five years and the generic marketing scheme utilized by defendant drug companies to explain this lack of identification.

Finally, the complaint states that "the defendants named herein constitute all of the known manufacturers

---

5. Plaintiffs have apparently abandoned the conspiracy count. Circuit Court Hearing Transcript, 3/28/77 (Vol. 21), p. 115. (Defendants' Appendix, 298a)

or distributors of stilbene derivatives during the time period in controversy: to wit, 1947 to 1964." (Plaintiff's original complaint, ¶ 17.)[6]

The answers of defendants generally deny the significant allegations of the complaint.

Motion for Summary Judgment

Defendants moved for a summary judgment under GCR 1963, 117.2(3) which states:

> "The motion for summary judgment shall state that the moving party is entitled to judgment in his favor because of any 1 of the following grounds:
>
> * * *
>
> "(3) That except as to the amount of damages there is no genuine issue as to any material fact, and the moving party is therefore entitled to judgment as as matter of law."

A motion under subsection 3 asks the court to test the factual foundation of the suit. The defendants have directed the court's scrutiny to three "factual deficiencies" in plaintiffs' case: 1) lack of proof that all defendants are before the court (as required by their alternative liability claim); 2) lack of evidence of concerted activity among the defendants in the promotion and manufacture of their estrogen products; and 3) failure to define the applicable "industry" for their "industry-wide" liability theory.

---

6. Plaintiffs' initial pleading also included a complaint for mandamus requesting that defendants affirmatively be required to notify women who may be afflicted by DES-related injuries so that they may join as plaintiffs, to establish a comprehensive screening program to identify women who may be injured, and to provide treatment for these women. This part of the complaint was dismissed without prejudice (Order, 1/20/75, Defendant's Appendix, 45a).

While defendants' subsection 3 motions were properly filed with the trial court, the trial judge never reached these factual questions, having disposed of the case by ruling that the plaintiffs' pleadings failed to state causes of action under alternative liability and concert of action theories.

Nor did the Court of Appeals address defendants' subsection 3 motion. The Court of Appeals panel confined its review to the correctness of the ruling on the subsection 1 motion.

Therefore, no lower court has yet evaluated the defendants' contention that no genuine issue of material fact exists in the present record. Since the issue has not been discussed below, we decline to review these claims. *Brill* v *Cherwin*, 346 Mich 507, 514; 78 NW2d 122 (1956); *Brewster* v *Martin Marietta Aluminum Sales, Inc*, 107 Mich App 639, 646; 309 NW2d 687 (1981).

However, it is clear that this motion has not been withdrawn or abandoned by the defendants. Therefore, unless it is, on remand and prior to this cause being tried, the trial court is required to hear and decide defendants' motion for summary judgment pursuant to GCR 1963, 117.2(3).

Defendants also assert that plaintiffs' affidavits in opposition to the defendants' motion for summary judgment were not made on personal knowledge as required by GCR 1963, 117.3 and 116.4. Necessarily encompassed within the trial court's decision as to the GCR 1963, 117.2(3) motion is the determination whether three affidavits of the parties are sufficient to meet the requirements of the court rule.

Defendants also sought summary judgment under GCR 1963, 117.2(1) which states:

"The motion for summary judgment shall state that the moving party is entitled to judgment in his favor because of any 1 of the following grounds:

"(1) the opposing party has failed to state a claim a claim upon which relief can be granted,

* * *

"(3) * * * and the moving party is therefore entitled to judgment as a matter of law."

A subsection 1 motion for summary judgment seeks to test the genuineness of a claim by challenging the *legal* adequacy of the pleadings. 1 Honigman & Hawkins, Michigan Court Rules Annotated (2d ed), 1982 Supp, p 142.

The standard used to assess the subsection 1 motion has been well stated:

"The test which the court should apply in considering motions under GCR 1963, 117.2(1) is whether plaintiff's claim, on the pleadings, is so clearly unenforceable as a matter of law that no factual development can possibly justify a right to recovery." *Crowther* v *Ross Chemical & Mfg Co*, 42 Mich App 426, 431; 202 NW2d 577 (1972).

In applying GCR 1963, 117.2(1), the trial court does not act as a factfinder, nor does the court attempt to probe the parties' ability to prove their allegations. Thus, the court accepts as true all well-pleaded[7] facts. *Bielski* v *Wolverine Ins Co*, 379 Mich 280, 283; 150 NW2d 788 (1967); *Hiers* v *Detroit Superintendent of Schools*, 376 Mich 225, 233; 136 NW2d 10 (1965).

Defendants find two deficiencies in the plaintiffs' allegations: first, plaintiffs have failed to establish the caus-

---

7. Pleading requirements are set forth in GCR 1963, 111.

ation in fact element which is required in any products liability action, and, second, plaintiffs assert a collective, industry-wide liability cause of action which is not recognized under Michigan law.

I. ALTERNATIVE LIABILITY COUNT

(A) *Asserted Deficiency in Pleading*

Defendants correctly assert that the threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer. *Piercefield* v *Remington Arms Co, Inc*, 375 Mich 85, 98-99; 133 NW2d 129 (1965). The plaintiff must produce evidence of a defect which caused the accident and trace that defect into the hands of the defendant.[8] *Caldwell* v *Fox*, 394 Mich 401, 410; 231 NW2d 46 (1975). See also 1 Hursh & Bailey, American Law of Products Liability 2d, § 1.41, p 125; Anno, 51 ALR3d 1344, 1349.

It is undisputed that all the plaintiffs in this action will not be able to meet the identification requirement. Paragraph 16 of the Thirteenth Amended Complaint reads: "some of the plaintiffs will be unable to identify the specific defendant that manufactured the injury-produc-

---

8. This identification requirement is, of course, a facet of the factual causation element of tort law. See, generally, Prosser, Torts (4th ed), § 41, pp 237, 239. The function of the causation element is to limit the scope of potential liability. If an actor were held responsible for all possible harms which which might flow from his acts, he could be deterred from performing useful and desirable activity. By adjusting the causation requirement, the court is able to strike a balance between deterring harmful behavior and encouraging useful activity.

Causation requirements also reflect common notions of moral responsibility or blame. Hart & Honore, *Causation in the Law* (Oxford: Clarendon Press, 1959) p 59; Malone, *Ruminations on Cause-In-Fact*, 9 Stan L Rev 60, 66 (1956); Becht & Muller, *The Test of Factual Causation in Negligence and Strict Liability Cases* (St. Louis: Washington Univ, 1961).

ing drug that was sold to their mothers in spite of all good-faith efforts to determine same".

Despite this hiatus in the pleadings, defendants recognize that plaintiffs would still have set forth a cause of action if their factual situation meets the requirements of the theory of alternative liability. Also called "clearly established double fault and alternative liability",[9] this procedural device shifts the burden of proof on the element of causation in fact to the defendants once an innocent plaintiff demonstrates that all defendants acted tortiously, but only one unidentifiable defendant caused plaintiff's injury. *Summers* v *Tice,* 33 Cal 2d 80; 199 P2d 1 (1948). If the defendants cannot meet this burden and exculpate themselves, joint and several liability will be imposed.

Defendants assert that plaintiffs' reliance on alternative liability is totally unsupportable by the pleaded facts of the present case. In order to evaluate this claim, we must explore the theory of alternative liability as it has developed in the jurisprudence of this state.

(B) *Alternative Liability*

The doctrine of alternative liability first received formal recognition[10] in the case of *Summers* v *Tice,* 33 Cal 2d 80; 199 P2d 1 (1948). In that case, plaintiff was injured by one shot during a hunting expedition. Plaintiff sued both of his hunting companions, claiming that both negligently shot at him, although he was unable to determine which one fired the specific shot that injured him.

---

9. Prosser, Torts (2d ed), § 41, p 243.

10. The *Summers* court recognized that the same result had been reached in an earlier case through a contorted use of the concept of concert of action. 33 Cal 2d 84.

The *Summers* court agreed, as a preliminary matter, that both defendants were at fault in having acted negligently toward the plaintiff. The court also recognized that plaintiff had failed to meet his traditional burden regarding cause in fact.[11] Only one shot had injured plaintiff; both defendants could not have shot it. Since the most the plaintiff could prove was a 50% probability that either of the defendants had caused the injury, plaintiff had failed to establish that either one of the defendants was more likely than the other to have caused the injury. 33 Cal 2d 84.

The court then decided—as a matter of policy—that it was preferable that the two wrongdoers, both of whom had acted negligently toward the plaintiff and had created the situation wherein plaintiff was injured, should bear the burden of absolving themselves rather than leaving the innocent plaintiff remediless. Therefore, the court placed the burden of proof on the issue of causation in fact upon the defendants.[12]

---

11. Prosser, *supra*, § 41, p 241, defines the burden of proof as follows:

> "[A plaintiff] must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result. A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant."

See also *Jordan* v *Whiting Corp*, 396 Mich 145, 151; 240 NW2d 465 (1976).

12. The court also reassigned the burden of proof regarding apportionment of damages. 33 Cal 2d 88. See 2 Restatement Torts, 2d, § 433B(2), p 441. Although the two issues were carefully distinguished by the *Summers* court, other courts have subsequently confused them. See, *e.g.*, *Shunk* v *Bosworth*, 334 F2d 309, 312 (CA 6, 1964) ("In the *Summers* case, the real difficulty was in apportioning the damages between the negligent defendants").

This rule is now embodied in 2 Restatement Torts, 2d, § 433B(3), pp 441-442.[13] Commentary to the Restatement agrees that the reason for the exception to traditional rules is to prevent the injustice of allowing proved wrongdoers to escape liability for an injury inflicted upon an innocent plaintiff "merely because the nature of their conduct and the resulting harm has made it difficult or impossible to prove which of them has caused the harm". Comment f, p 446. Accord, *Bowman* v *Redding & Co,* 145 US App DC 294, 305; 449 F2d 956 (1971).

This policy has found expression in the opinions of this state's courts. For example, *Benson* v *Ross,* 143 Mich 452; 106 NW 1120 (1906), presented a fact situation quite similar to *Summers.* Three defendants were taking turns shooting a single rifle when one of the shots struck the plaintiff. Although the plaintiff was unable to identify which one of the three negligent defendants fired the injury-causing shot, the Court found that the plaintiff had alleged sufficient facts to withstand a motion for directed verdict, relying on a concert of action theory.

This principle was also developed in *Holloway* v *General Motors Corp (On Rehearing),* 403 Mich 614, 626, 628; 271 NW2d 777 (1978), in which the question arose whether a plaintiff in a products liability action must establish the specific cause of the defect among alternative possible causes. In that case, testimony showed that the break in a ball-joint assembly may have been due to a defect in design, material, assembly, or a combination of design and material. The Court found that greater specificity in

---

13. Section 433B(3) provides:

"(3) Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm."

identifying the defect was not required for two reasons: 1) the purpose of tort law is to compensate injured persons (not merely to deter the manufacture of a specific product defect, a goal which would place a premium on defect identification), and 2) plaintiff was not at fault in her inability to produce more specific evidence of the defect and had not been deficient in her duty to prove the particular defect " 'by the most accurate evidence reasonably available' ". The Court recognized that the situation was "analogous" to the theory of alternative liability expressed in *Summers* v *Tice*. 403 Mich 625, fn 15.

Finally, the same equitable adjustment of burden of proof appears in a line of apportionment of damages cases. In *Maddux* v *Donaldson*, 362 Mich 425; 108 NY2d 33 (1961), the plaintiff was involved in a multiple collision of automobiles suffering two separate collisions, each of which contributed to her injuries. Initially, the trial court dismissed the case because the plaintiff was unable to present any evidence that the damages could be apportioned. This Court disagreed, recognizing the injustice of the plaintiff's burden:

> "When we impose upon an injured plaintiff the necessity of proving which impact did which harm in a chain collision situation, what we are actually expressing is a judicial policy that it is better that a plaintiff, injured through no fault of his own, take nothing, than that a tort-feasor pay more than his theoretical share of the damages accruing out of a confused situation which his wrong has helped to create. The mere statement of the policy exposes its aberrations. It is at war with at least the last hundred years of judicial progress." 362 Mich 430.

Therefore, rather than deny an innocent plaintiff recovery, the Court held that a plaintiff who proves an indivisible in-

jury is relieved of the burden of apportioning damages; instead, the defendants are held jointly and severally liable. This equitable policy has frequently been reaffirmed. See, *e.g., Brownell* v *Brown,* 407 Mich 128; 283 NW2d 502 (1979); *Michie* v *Great Lakes Steel Division,* 495 F2d 213 (CA 6, 1974), *cert den* 419 US 997 (1974); *Oakwood Homeowners Ass'n, Inc* v *Ford Motor Co,* 77 Mich App 197; 258 NW2d 475 (1977).

Clearly then, the policy underlying the theory of alternative liability has been adopted in this state. We now formally express our approval of the theory of alternative liability.

We observe, however, that the reasoning of *Summers,* the polestar case for alternative liability, does not define a theory of recovery that provides a neatly fitting analytical template for application to this case. The situation in *Summers* is substantially and significantly distinguishable from this DES litigation, although it is not sufficiently so to make the theory of alternative liability entirely inapplicable. The requirements of the alternative liability theory in *Summers* must be modified, however, to accommodate the unique facts of this unusual litigation.

Summers involved one plaintiff and two defendants. This case involves 180 plaintiffs, some of whom were injured directly and some derivatively, and at least 16 defendants. In *Summers,* all the parties who could have caused harm to the single plaintiff were before the court. Here, whether the plaintiffs have brought all defendants before the court is a contested issue. The plaintiffs claim they have sued all known manufacturers of stilbene derivatives who promoted the drugs to the medical profession in Michigan for use in pregnancy during the period between 1947 and 1964. Defendants assert, however, that there

are several hundred defendants that should be before the court if our requirement of the presence of all those who could have caused the plaintiff's injury is to be met.

In *Summers,* the asserted negligence and the injury resulting therefrom, and the activity of all the parties, occurred at essentially the same time and at one place, providing so-called simultaneity. Here, the alleged tortious activity occurred over a span of almost two decades and conceivably throughout the United States.

Perhaps the most fundamental, and arguably the most important, factual difference between *Summers* and this case is that in *Summers* each defendant was negligent toward the sole plaintiff; each could have caused the injury to the plaintiff although only one in fact did so. Here, the plaintiffs do not even claim that each of the defendants was negligent toward each of the plaintiffs. Therefore, each of the defendants in this case could not have caused injury to each of the plaintiffs. Stated differently, in *Summers,* each defendant was negligent toward *the* plaintiff; here, each defendant was negligent toward *a* plaintiff, but each defendant was not negligent toward *each* plaintiff. Thus, all defendants were not negligent toward each plaintiff, and each defendant could not have caused each plaintiff's injury.

Although the rationale of the alternative liability theory in *Summers* is not squarely applicable to this DES litigation partly because the facts of the two cases are so distinctly different, the theory as first detailed in *Summers* can nevertheless be tailored to accommodate the unique facts of this case, and in fairness ought to be. It should be understood, however, that in approving application of alternative liability to this case, we are not only extending the *policy* of traditional alternative liability as espoused in *Summers* to accommodate the facts; we are actually

fashioning and approving a new DES-unique version of alternative liability.

The requirements which the plaintiffs must meet before availing themselves of the eased burden of proof may be garnered from the cases above. First, it must be shown that all the defendants have acted tortiously, *cf. Shunk* v *Bosworth,* 334 F2d 309 (CA 6, 1964); second, that the plaintiffs have been harmed by the conduct of one of the defendants (in order to support this second requirement, the plaintiffs must bring before the court all the actors who may have caused the injury in fact);[14] third, that the plaintiffs, through no fault of their own, are unable to identify which actor caused the injury.

---

14. Failure to meet this requirement has resulted in summary judgments in the majority of DES cases which attempted to utilize this theory. See, *e.g., Ryan* v *Eli Lilly & Co,* 514 F Supp 1004, 1016-1017 (D SC, 1981); *Namm* v *Charles E Frosst & Co,* 178 NJ Super 19, 32-33; 427 A2d 1121 (1981); *Sindell* v *Abbott Laboratories,* 26 Cal 3d 588, 602-603; 163 Cal Rptr 132; 607 P2d 924 (1980); *Gray* v *United States,* 445 F Supp 337, 338 (SD Tex, 1978).

As explained by the *Sindell* court, p 603:

> "[T]he possibility that any of the five defendants [chosen from among a possible 200 companies] supplied the DES to plaintiff's mother is so remote that it would be unfair to require each defendant to exonerate itself. There may be a substantial likelihood that none of the five defendants joined in the action made the DES which caused the injury, and that the offending producer not named would escape liability altogether."

We also note that comment h to 2 Restatement Torts, 2d, § 433B(3), p 446 suggests possible modification of the requirement that all defendants must be joined.

> "It is possible that cases may arise in which some modification of the rule stated may be necessary because of complications arising from the fact that one of the actors involved is not or cannot be joined as a defendant, or because of the effect of lapse of time, or because of substantial differences in the character of the conduct of the actors or the risks which they have created."

On the basis of the pleadings of this case, it is not necessary to consider the appropriateness of modifying this requirement.

In that connection, plaintiffs must make a genuine attempt to locate and identify the tortfeasor responsible for the individual injury. The genuineness of the attempt to do so is to be measured by the traditional due diligence standard, and it is the trial court's duty to ascertain whether a duly diligent effort on the part of a plaintiff has been made. A trial court finding of a lack of diligence will preclude plaintiffs' resort to DES-modified alternative liability. We also restrict, for the time being, the use of this theory of recovery to those allegations sounding in negligence. Plaintiffs may not resort to the theory for warranty allegations or for strict liability allegations.[15]

Plaintiffs' ability to meet these conditions precedent will allow them to avail themselves of DES-modified alternative liability, thus relieving them of the traditional burden of proof of causation in fact. We emphasize that although plaintiffs are absolved of identifying specifically the tortfeasor who caused each specific harm, their burden of proof as to other aspects of causation is not lessened.

In that connection, as necessary corollaries of shifting the burden of proving causation in fact and the requirement that plaintiffs bring all potential tortfeasors before the Court, the plaintiffs are required to prove the following:

1) that all defendants distributed or manufactured one or more of the three drugs involved: DES, DSD, or dienestrol;

2) that the female plaintiffs' mothers ingested DES, DSD, or dienestrol (it is not sufficient that plaintiffs prove merely that their mothers ingested *a* synthetic estrogen

---

15. We read the briefs and arguments of the plaintiffs as asserting the theory of alternative liability in respect to the negligence but not the other theories of recovery, and accordingly we reserve the question whether the alternative liability theory is applicable on another theory of recovery.

as there may be other synthetic estrogens prescribed for the same reason which are not at issue here. Conceivably plaintiffs could satisfy this requirement by showing that no other synthetic estrogens prescribed for the same purposes as DES, DSD or dienestrol were prescribed for during the relevant period);

3) that the female plaintiffs' mothers ingested DES, DSD, or dienestrol manufactured or distributed in Michigan;[16] and

4) that DES, DSD, and dienestrol each caused the type of injury of which the plaintiffs complain; that is, plaintiffs must prove that these three drugs are essentially identical in their injury-producing results.

We note in passing that defendants' access to evidence of causation is not a relevant factor. The California court in *Summers* did mention that "[o]rdinarily defendants are in a far better position to offer evidence to determine which one caused the injury". 33 Cal 2d 86. However, the requirements of better access to evidence and its counterpart, exclusive control, are more correctly facets of the doctrine of *res ipsa loquitur*. See *Ybarra* v *Spangard*, 25 Cal 2d 486; 154 P2d 687 (1944); *Anderson* v *Somberg*, 67 NJ 291, 305; 338 A2d 1 (1975). Even as a factor within that doctrine, the defendant's access to evidence as a controlling consideration has been criticized. See, *e.g.* Prosser, *supra*, § 39, p 225.

The burden of proof that is shifted to each defendant is to prove by a preponderance of the evidence that it neither produced nor marketed the DES, DSD, or dien-

---

16. The complaint alleges that "all of the known manufacturers of stilbene derivatives who promoted, in Michigan, said drugs to the medical profession for use in pregnancy" during the relevant period are before the Court as defendants. (Plaintiff's 14th amended complaint, ¶ 14.)

estrol ingested by female plaintiffs' mothers. A defendant may, of course, meet that burden by proving that it did not market or produce DES, DSD, or dienestrol during the period in which plaintiffs' mother was exposed to the drug or by showing that its products were not available in the relevant geographical area in which plaintiffs' mothers acquired the drug.

In sum, alternative liability will be applied in cases in which all defendants have acted tortiously, but only one unidentifiable defendant caused plaintiff's injury. If a plaintiff brings all the possible defendants into court and establishes the other elements of the underlying cause of action, the court should equitably shift an onerous burden of causation in fact to the defendants. If the defendants are unable to exonerate themselves, joint and several liability results.

(C) *Plaintiffs' Allegations*

In light of this examination of the requirements of alternative liability, it is apparent that some plaintiffs have alleged sufficient facts to withstand summary judgment on the causation issue.

Plaintiffs have alleged that all defendants acted negligently in manufacturing and promoting preparations of dienestrol, DES, and DSD, despite scientific research indicating that such drugs were likely to cause cancer. Thirteenth Amended Complaint, ¶¶ 2 and 7. Plaintiffs also state that all the manufacturers who promoted the drugs for use during pregnancy in Michigan during the time period 1947 to 1964 are before the Court. Thirteenth Amended Complaint, ¶ 14.

Difficulties arise, however, in that not all plaintiffs have alleged that they are unable to identify the manu-

facturer of the product that their mothers ingested. As of the fourteenth amended complaint, approximately 70 plaintiffs allege that they are able to identify the manufacturer of the drug which injured them (¶ 20).

As we have seen, the *raison d'etre* of alternative liability is to shift an onerous proof requirement where to do otherwise would leave an innocent plaintiff remediless. Where plaintiffs are *able* to identify the causation in fact of their injury, traditional tort remedies must be used to secure relief. Accord, *Lyons* v *Premo Pharmaceutical Labs, Inc*, 170 NJ Super 183, 192; 406 A.2d 185 (1979).

Of course, pleading practices in Michigan permit the assertion of inconsistent claims. GCR 1963, 111.9. Even in this situation, where proof of one claim must defeat the existence of another, the plaintiff is allowed to present both claims. The winnowing of issues and scrutiny of claims is accomplished by discovery procedures, pretrial conferences, and summary judgment motions, not through pleading technicalities. Therefore, plaintiffs' antithetical pleadings alone do not warrant summary judgment relief.[17]

On the other hand, once plaintiffs prove the identity of the manufacturer of the DES product ingested, the option of alternative liability is no longer available to them.

Presently, 113 plaintiffs have alleged that they are unable to identify the manufacturer of the product which harmed them. They assert that they are blameless in their

---

17. On this point, we must disagree with the Court of Appeals opinion which seems to indicate that plaintiffs must opt for one theory or another, but may not allege both. The Court of Appeals stated:

> "Those [plaintiffs] who have already amended their complaint to allege a sole tortfeasor may either allege joint and alternative liability or stand on the most recent amendment." 94 Mich App 77, fn 6.

inability to meet the identification requirement (Original Complaint, ¶ 22, Defendants' Appendix, 9a). These plaintiffs explain their failure to name a specific manufacturer by citing legislation requiring pharmacists to maintain prescription drug records for only five years, MCL 338.1119; MSA 14.757(19), as amended by MCL 333.17751; MSA 14.15(17751), and the defendants' use of a generic marketing scheme to promote the product (Thirteenth Amended Complaint, ¶ 17, Defendants' Appendix, 287a). These pleadings constitute sufficient allegations to withstand summary judgment under GCR 1963, 117.2(1).

Finally, the 70 plaintiffs who allege that they are able to identify the manufacturer of the product which harmed them may bring forth their proofs at trial. If they are unable to establish the required identification, they have the option of pursuing their alternative liability theory.

II. CONCERT OF ACTION

(A) *Allegations of Novel Theories*

Defendants also request summary judgment claiming that plaintiffs improperly rely on theories of liability not recognized in Michigan.

Plaintiffs' complaint alleges that defendants are "jointly and severally responsible" for the alleged injuries.

Clearly, the concept of joint and several liability is not foreign to this state. See, *e.g.*, *Cuddy* v *Horn*, 46 Mich 596; 10 NW 32 (1881); *King* v *Herfurth*, 306 Mich 444; 11 NW2d 198 (1943). Various rationales have been argued to justify its imposition in the present case: concert of action, enterprise liability, as enunciated in *Hall* v *E I DuPont de Nemours & Co*, 345 F Supp 353 (ED NY 1972), market share liability, as set forth in *Sindell* v *Abbott Laboratories*,

Inc, 26 Cal 3d 588; 163 Cal Rptr 132; 607 P2d 924 (1980), *cert den* 449 US 912 (1980), or some other modification of a collective, industry-wide liability.[18] Of these varied theories, only concert of action is recognized in Michigan.

While it is not this Court's intention to be unreceptive to developing theories in the everchanging matrix of the law, neither should the Court adopt new theories where no need exists. Only when traditional concepts fail to meet the demands which are placed upon them must novel responses develop to fill the void and answer society's need for equitable loss distribution.

In the present case, plaintiffs have not presented this Court with any innovative legal claims to evaluate. They have not urged us to adopt "enterprise", "industry-wide", or "market share" liability. When the parties thus feel that traditional theories are sufficient, this Court will not assume the task of evaluating relief not requested.

(B) *Concert of Action*

Plaintiffs, however, do seek to proceed on the traditional theory of concert of action. This theory, although not developed to ease plaintiff's traditional burden of

---

18. Throughout the country, commentators are wrestling with the problems presented in the DES litigation. Their analyses are thoughtful and helpful. See, *e.g.*, Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L Rev 963; Comment, *Market Share Liability: An Answer to the DES Causation Problem*, 94 Harv L Rev 668 (1981); Coggins, *Industry-wide Liability*, 13 Suffolk L Rev 980 (1979); Fischer, *Products Liability—An Analysis of Market Share Liability*, 34 Vand L Rev 1623 (1981); Comment, *DES: Alternative Theories of Liability*, 59 J Urban L 387 (1982); Endress & Sozio, *Market Share Liability: A One Theory Approach Beyond DES*, 1983 Det C L Rev 1; Comment, *Market Share Liability for Defective Products: An Ill-Advised Remedy for the Problem of Identification*, 76 Northwestern U L Rev 300 (1981).

proof of causation,[19] may have that effect. If plaintiffs can establish that all defendants acted tortiously pursuant to a common design, they will all be held liable for the entire result.

The concept is perhaps most clearly illustrated in the racing context. If three drivers join in a drag race, as a result of which one pedestrian is injured, all three may be held liable. Thus a legal fiction is created: all three drivers are found to be the cause in fact, although only one driver may have actually struck the pedestrian.

In order to withstand a motion for summary judgment based on a failure to state a cause of action, a plaintiff need only allege that the defendants were jointly engaged in tortious activity as a result of which the plaintiff was harmed. *Walters* v *Sargent,* 390 Mich 775; 210 NW2d 315 (1973); *McCoy* v *DeLiefde,* 376 Mich 198; 135 NW2d 916 (1965) (opinion of Souris, J.).

Unlike the procedural device of alternative liability, a concert of action case does not require that the plaintiff be unable to identify the specific defendant who caused his injury in fact. The plaintiff is usually able to make that determination. See, *e.g., Gaufin* v *Valind,* 268 Mich 269; 256 NW 335 (1934); *Mahnke* v *Freer,* 126 Mich 572; 85 NW 1099 (1901); *King* v *Herfurth,* 306 Mich 444; 11 NW2d 198 (1943).[20] Such identification does not preclude liability on a concert of action theory.

---

19. The theory seems to have developed to deter hazardous group behavior, rather than in response to plaintiff's causation burden. See Comment, *DES and a Proposed Theory of Enterprise Liability,* 46 Fordham L Rev 963, 979; *Lyons* v *Premo Pharmaceutical Labs, Inc,* 170 NJ Super 183, 192; 406 A2d 185 (1979).

20. But *cf. Fisher* v *Rumler,* 239 Mich 224; 214 NW 310 (1927); *Walters* v *Sargent,* 390 Mich 775; 210 NW2d 315 (1975).

Here plaintiffs have alleged that defendants acted together in negligently manufacturing and promoting drugs which were ineffective and dangerous, were inadequately tested, and were distributed without sufficient warnings. These allegations are sufficient to withstand summary judgment under GCR 1963, 117.2(1). Those plaintiffs who have alleged that a specific manufacturer caused their injuries are not precluded from this cause of action.

CONCLUSION

Plaintiffs have made sufficient allegations to support their concert of action claim. Additionally, those plaintiffs who, on the standard we have enunciated, demonstrate inability to identify the manufacturer of the product which harmed them and who sustain the remaining burdens of proof as we have defined them, may take advantage of the burden-shifting feature of the alternative liability theory to withstand summary judgment on the causation issue of the negligence claims.

The number and posture of the parties and the novelty and complexity of the issues incidental to the theory of recovery we approve today suggest a major challenge to the trial management skills of the trial judge and the advocacy skills of trial counsel. In addition, unanticipated jurisprudential procedural and substantive issues will inevitably arise. We do not presume the prescience to anticipate all of them at this remove, let alone address and resolve them. We are deciding the issues before us today in a virtual factual vacuum. The fairness of the application at trial of the theory of alternative liability remains to be seen. A factual record may reveal a number of unanticipated inequities affecting *any* of the parties in trying to a verdict the new cause of action we approve today. One defendant asserts, for example, that it sold approximately

$75 worth of DES in Michigan during 1953. Whether that can be proved remains to be seen. If it is, difficult questions of allocation of damages may be presented. We are not unmindful of the possibility of such difficulties, but neither do we attempt to anticipate and reconcile them in advance of trial.

Thus, we explicitly reserve judgment concerning the validity of *any* verdict that may result from a trial of the cause of action we have approved.

The judgment of the Court of Appeals, as modified, is affirmed and the case is remanded to the Third Judicial Circuit Court for proceedings consistent with this opinion.

/s/ G. Mennen Williams
/s/ Charles L. Levin
/s/ Thomas Giles Kavanagh
/s/ Michael F. Cavanagh
/s/ James H. Brickley
/s/ James L. Ryan

B. Judgment Order of Supreme Court of Michigan pursuant to Opinion, dated March 26, 1984, and April 27, 1984 Certification of Judgment Order

STATE OF MICHIGAN—ss.

I, CORBIN R. DAVIS, Clerk of the Michigan Supreme Court, hereby certify that the annexed is a true and correct copy of the Judgment Order in Abel et al v Eli Lilly and Company et al No 64712 entered February 6, 1984 and that I have compared it with the original document as the same appears in the files and records of this Court and that it is a true transcript therefrom, and the whole of said record.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said Supreme Court at Lansing this 27th day of April, 1984.

/s/ Corbin R. Davis
Clerk

AT A SESSION OF THE SUPREME COURT OF THE STATE OF MICHIGAN, Held at the Supreme Court Room, in the City of Lansing, on the 6th day of February in the year of our Lord one thousand nine hundred and eighty-four.

Present the Honorable
G. Mennen Williams,
Chief Justice

Thomas Giles Kavanagh,
Charles L. Levin,
James L. Ryan,
James H. Brickley,
Michael F. Cavanagh,
Patricia J. Boyle,
Associate Justices.

SC 64712
CoA 77-3421
LC 74-030-070-NP

GAIL ABEL, et al,
Plaintiffs-Appellees,

v

ELI LILLY and COMPANY, et al,
Defendants-Appellants.

This cause having been brought to this Court by appeal from the decision of the Court of Appeals and having been argued by counsel and due deliberation having been had thereon by the Court, IT IS HEREBY ORDERED that the judgment of the Court of Appeals is AFFIRMED as modified and the cause is REMANDED to the Circuit Court for the County of Wayne for further proceedings in conformity with the opinion filed herein.

STATE OF MICHIGAN—ss.

I, CORBIN R. DAVIS, Clerk of the Supreme Court of the State of Michigan, do hereby certify that the foregoing is a true and correct copy of an order entered in said court in said cause; that I have compared the same with the original, and that it is a true transcript therefrom, and the whole of said original order.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said Supreme Court at Lansing this 26th day of March in the year of our Lord one thousand nine hundred and eighty-four.

/s/ Corbin R. Davis
Clerk

(SEAL)

C. Order Denying Rehearing, Supreme Court of Michigan, dated March 26, 1984

AT A SESSION OF THE SUPREME COURT OF THE STATE OF MICHIGAN, Held at the Supreme Court Room, in the City of Lansing, on the 26th day of March in the year of our Lord one thousand nine hundred and eighty-four

Present the Honorable
G. Mennen Williams,
Chief Justice

Rehearing Nos.
106, 107

Thomas Giles Kavanagh,
Charles L. Levin,
James L. Ryan,
James H. Brickley,
Michael F. Cavanagh,
Patricia J. Boyle,
Associate Justices.

SC 64712
CoA 77-3421
LC 74-030-070-NP

GAIL ABEL, et al,
Plaintiffs-Appellees,

v

ELI LILLY and COMPANY, et al,
Defendants-Appellants.

In this cause motions for rehearing are considered and, on order of the Court, are hereby DENIED. Plaintiffs' motion for immediate consideration is GRANTED. The motion to sever certain defendants is DENIED as moot. The motion by plaintiffs to tax costs for vexatious proceedings is considered and is DENIED for the reason that the Court is not persuaded such relief should be granted.

STATE OF MICHIGAN—ss.

I, CORBIN R. DAVIS, Clerk of the Supreme Court of the State of Michigan, do hereby certify that the foregoing is a true and correct copy of an order entered in said court in said cause; that I have compared the same with the original, and that it is a true transcript therefrom, and the whole of said original order.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said Supreme Court at Lansing this 26th day of March in the year of our Lord one thousand nine hundred and eighty-four.

/s/ Corbin R. Davis
Clerk

(SEAL)

D. Opinion of the Michigan Court of Appeals, dated December 5, 1979

STATE OF MICHIGAN
COURT OF APPEALS

Docket # 77-3421

GAIL ABEL, et al,
Plaintiffs-Appellants,

v

ELI LILLY AND COMPANY, ABBOTT LABORATORIES, THE BLUE LINE CHEMICAL COMPANY, BURROUGHS WELLCOME COMPANY, CENTRAL PHARMACAL COMPANY, COLE PHARMACAL COMPANY, KREMERS-URBAN COMPANY, McNEIL LABORATORIES, INC., MERCK, SHARPE & DOHME, REXALL DRUG COMPANY, WILLIAM J. RORER, INC., S. J. TUTAG AND COMPANY, SCHERING CORPORATION, E. R. SQUIBB AND SONS, INC., UPJOHN COMPANY AND VALE CHEMICAL COMPANY,
Defendants-Appellees.

BEFORE: R. M. Maher, P.J., and Bronson and A. E. Moore*, JJ.

R. M. MAHER, P.J.

Plaintiffs appeal as of right from an order of the Wayne County Circuit Court granting partial summary judgment in favor of defendants. This is a multiple-plaintiff, multiple-defendant products liability action involving a widely-distributed prescription drug. The trial judge ruled that each plaintiff, in order to state a cause

---

*Former circuit judge, sitting on the Court of Appeals by assignment.

of action sufficient to withstand a motion for summary judgment, must identify in the complaint which of the defendants allegedly manufactured the specific product which caused his or her harm. Those plaintiffs who could not name the particular defendant whose product harmed them were no-caused. Those plaintiffs who named a particular defendant had their claims against all other defendants dismissed.

This action was commenced on September 17, 1974, when plaintiffs filed a complaint alleging that defendants are jointly and severally liable for negligence, breach of express and implied warranties, fraud and conspiracy. The complaint was amended 14 times. Specifically, the complaint alleged that defendants were negligent in failing to perform adequate tests on the synthetic estrogens known as dienestrol, diethylstilbestrol or diethylstilbestrol diproprionate (hereinafter DES);[1] in distributing DES and promoting it for the prevention of miscarriages in pregnant women when they knew, or in exercise of due care would have discovered, that it presented a danger to the child *in utero;* and in failing to warn consumers of the dangers inherent in use of DES to prevent miscarriages. The complaint further alleged that DES was defective in that it was not effective in the prevention of miscarriage, in that it caused the development of cancerous or precancerous lesions in the vaginas of females whose mothers consumed DES while pregnant, and in that the product carried inadequate warnings of the danger presented to unborn children whose mothers consumed DES while pregnant. The female plaintiffs alleged that they developed cancerous or precancerous conditions as a result of the consumption of DES by their mothers while plaintiffs were *in utero.* The male plaintiffs are husbands of the female plaintiffs.

Plaintiffs' complaint also alleged that the defendants named therein constitute all of the known manufacturers of DES whose products were distributed in Michigan during the relevant time period, that one or more of the named defendants caused the harm to each of the plaintiffs, but that some plaintiffs were unable to discover which particular defendant caused their harm because of the destruction of medical and pharmacy records. Plaintiffs further alleged that the inability to name the individual defendant should not bar recovery, in that defendants were jointly and severally liable for the harm to plaintiffs because all defendants acted wrongfully and only the drug companies named in the suit could have caused plaintiffs' harm. The complaint further alleged that defendants were collectively liable for plaintiffs' harm.

Discovery and other proceedings, for the most part irrelevant to this appeal, consumed more than two years and produced a voluminous record. On February 1, 1977, defendants filed a motion for partial summary judgment alleging (1) that they were entitled under GCR 1963, 117.2(1), to summary judgment of no cause of action against all plaintiffs who were unable to name the manufacturer of the particular item which caused their injury; (2) that plaintiffs' allegations of collective, industry-wide liability did not state a cause of action cognizable under the laws of the State of Michigan requiring summary judgment as to that claim under GCR 1963, 117.2(1); and (3) that there existed no genuine issue as to any material fact regarding the conspiracy or concert of action count and that defendants were entitled to summary judgment as a matter of law under GCR 1963, 117.2(3). Defendants' motion was supported by affidavits which stated that more than 300 manufacturers were listed in standard reference works as offering DES for sale during the relevant time

period. In opposition to the motion, plaintiffs produced affidavits to the effect that the list of defendants was "inclusive of" manufacturers whose products were being distributed in Michigan during the relevant time period.

On May 16, 1977, the trial court issued its opinion granting summary judgment of no cause of action (1) for all defendants against those plaintiffs unable to allege specifically the defendant whose product harmed them; (2) for all defendants other than the defendant named, against those plaintiffs who alleged that a particular defendant caused their harm; and (3) for all defendants against all plaintiffs on the claim of collective liability. All judgments were granted pursuant to GCR 1963, 117.2 (1).

On August 25, 1977, plaintiffs filed their 14th amended complaint, in which 70 plaintiffs alleged that a particular defendant caused their harm. On the same date, the trial court entered a final order granting partial summary judgment for defendants in accordance with its opinion of May 16, 1977. On September 7, 1977, claim of appeal was filed in this Court on behalf of 182 plaintiffs.

Plaintiffs argue on appeal that the trial court erred, first, in holding that each plaintiff must allege which defendant produced the drug which harmed her in order to state a cause of action and, second, in holding that in their allegations of collective liability plaintiffs failed to state a claim upon which relief may be granted. In reviewing plaintiffs' claims of error, we must keep in mind certain rules. We note first of all that a motion for summary judgment under GCR 1963, 117.2(1), merely tests the legal sufficiency of the pleadings. *Todd* v *Bigelow*, 51 Mich App 346; 214 NW2d 733 (1974). The test is whether plaintiffs' claim as pled is so clearly unenforceable as a matter of law that no factual development can possibly

justify a right to recovery. *Crowther* v *Ross Chemical & Mfg Co*, 42 Mich App 426; 202 NW2d 577 (1972). Further, we must bear in mind that a motion under Rule 117.2(1) does not test plaintiffs' ability to prove their allegations. *Lompre* v *Venetjoki*, 76 Mich App 521; 527 NW2d 151 (1977). The trial court in ruling on the motion must accept as true all well pleaded facts in the complaint. *Stewart* v *Troutt*, 73 Mich App 378; 251 NW2d 594 (1977). On review, this Court must apply the same rules. *Lincoln Park Detention Officers* v *Lincoln Park*, 76 Mich App 358; 256 NW2d 593 (1977).

The remedy afforded consumers as against sellers and manufacturers of defective goods, which has been termed "products liability," has been described as "not [a] statutory, but essentially a judicial development which the courts should be free to develop further." *Parish* v *B F Goodrich Co*, 395 Mich 271; 235 NW2d 570 (1975). See also *Moning* v *Alfono*, 400 Mich 425; 254 NW2d 759 (1977). It has roots in both contract and tort law, but is distinct from both. See discussion in *Cova* v *Harley Davidson Motor Co*, 26 Mich App 602; 182 NW2d 800 (1970). In Michigan, two theories of recovery are recognized in the area of products liability: negligence and breach of implied warranty. *Johnson* v *Chrysler Corp*, 74 Mich App. 532; 254 NW2d 569 (1977). Under a negligence theory, the plaintiff must establish the traditional common-law elements of duty, breach, damage and causation. See *Moning* v *Alfono, supra*. To establish breach of implied warranty, the plaintiff must show that a defect in the product, attributable to the manufacturer, caused his injuries. *Smith* v *E R Squibb & Sons*, 405 Mich 79; ..... NW2d ..... (1979).

It is self-evident that the defective product must be shown to have come from defendant rather than some

other manufacturer, for if defendant has neither acted negligently nor breached his implied warranty he can incur no liability. See Anno: *Products Liability: Necessity and sufficiency of identification of defendant as manufacturer or seller of product alleged to have caused injury*, 51 ALR3d 1344. In the ordinary case, the plaintiff knows (or believes he knows) the identity of the sole tortfeasor, and the proofs are directed toward establishing the wrongful conduct of the tortfeasor and the causal connection between that conduct and the harm to plaintiff. Occasionally plaintiff alleges that one or more tortfeasors have acted wrongfully and that one or the other, or both, caused his injury. See, for example, *Jordan* v *Whiting Corp*, 396 Mich 145; 240 NW2d 468 (1976) (estate of crane repairman electrocuted by crane sues manufacturer of crane parts, assembler of crane and installer of wiring), *Elsasser* v *American Motors Corp*, 81 Mich App 379; 265 NW2d 339 (1978) (plaintiff injured by fire resulting from collision which ruptured gas tank sues driver of car which struck his and manufacturer of his car). In such a case plaintiff seeks to prove wrongful conduct on the part of all defendants and resulting harm to himself. A defendant in such a case, in addition to denying that his conduct was wrongful, often defends on grounds that his negligence or his defective product has not been shown to be a proximate cause of plaintiff's injury. See discussion in *Dooms* v *Stewart Bolling & Co*, 68 Mich App 5; 241 NW2d 738 (1976).

Those cases in which plaintiff alleges that his injury was caused by more than one tortfeasor may be variously classified. Prosser divides so-called joint torts according to the rationale for imposing joint and several liability into eight classes, including those involving concerted action and cases of alternative liability.[2] The claims asserted in the case at bar fall into two categories: concerted ac-

tion and alternative liability.[3] Plaintiffs allege that all defendants acted wrongfully in producing and marketing a defective product, and that each plaintiff was injured by the product of one or the other defendant. All defendants acted wrongfully, and one (but only one) caused the harm to plaintiff; therefore, they are alternatively liable. Plaintiffs also allege that all defendants acting in concert caused the marketing of DES, and that this concerted activity is the cause of plaintiffs' injuries. All defendants having acted together to cause all the harm, they are jointly and severally liable therefor.

Defendants argue in their brief on appeal that permitting plaintiffs to proceed to trial on their concert of action theory is without precedent and is tantamount to imposing liability on an innocent manufacturer for the actions of his fellows. This argument misperceives the nature of plaintiffs' claim. It is well-established that if two or more persons engage negligently in concerted activity, and as a result plaintiff is injured, all are liable even though only one directly caused the injury. *McCoy* v *DeLiefde*, 376 Mich 198; 135 NW2d 916 (1965) (opinion of Souris, J.). Liability is imposed on all because all have joined in breaching their duty of care to plaintiff, and he was injured as a result of that breach. Plaintiffs in their complaint allege that defendants acted in concert to produce and market ineffective and dangerous products, without adequate testing and without adequate warnings. These allegations are sufficient to state a cause of action, and summary judgment as to the concerted activity claim was improper, *McCoy* v *DeLiefde, supra*.

Defendants also argue that there is no evidence that defendants acted in concert in producing and marketing DES, and claim that no such proof exists. It is sufficient to say that a motion for summary judgment under GCR

1963, 117.2(1) tests only the sufficiency of the pleadings. *Lompre* v *Venetjoki, supra.* Resolution of this disputed fact question must await trial, *McCoy* v *DeLiefde, supra.*[4]

The concert of action claim is a true joint tort, and once the fact of a tortfeasor's liability is established, its extent is clear: he is jointly and severally liable for the entire amount of damages, although he may be entitled to contribution from his fellow tortfeasors. See Prosser, *Joint Torts and Several Liability,* 25 Cal L Rev 413 (1937), *Caldwell* v *Fox,* 394 Mich 401; 231 NW2d 46 (1975). Although a joint tortfeasor may (and usually does) dispute the fact of liability, he may not dispute the extent thereof. He may seek to show that only his codefendant, and not he, acted wrongfully, but not that his fellow tortfeasor caused all or the greater portion of the damage and should therefore pay a greater share. See *Sexton* v *American Aggregates,* 60 Mich App 524; 231 NW2d 449 (1975). Even if defendant caused no harm himself, he is liable for the harm caused by his fellows because all acted jointly. *Benson* v *Ross,* 143 Mich 452; 106 NW 1120 (1906).

The alternative liability theory, on the other hand, involves not a joint tort but independent acts by two or more tortfeasors, all of whom have acted wrongfully but only one of whom has injured plaintiff. Joint and several liability is imposed, not because all are responsible for the damage, but because it is impossible to tell which one is responsible. Rather than deny the innocent plaintiff his recovery because he cannot prove which of two or more wrongdoers injured him, the courts impose joint liability on all wrongdoers. In cases of alternative liability, a defendant is free to absolve himself of blame and cast the entire burden on his fellows, even if it be shown that he acted wrongfully, but must bear the burden of proving that his wrongful act was not the cause of plaintiff's injury. See

Summers v *Tice*, 33 Cal 2d 80; 199 P2d 1; 5 ALR2d 91 (1948). Prosser has described the situation typified by *Summers, supra,* as "clearly established double fault and alternative liability." Prosser, *Torts* (3d ed), § 41, p 247. This apt description helps to distinguish these cases from the situation in which there is but a single act of negligence by one of multiple defendants, but it is not clear which defendant committed that act. See Annotation: *Liability of Several Persons Guilty of Acts One of Which Alone Caused Injury, in Absence of Showing as to Whose Act Was the Cause,* 5 ALR2d 98, 100. Joint and several liability is imposed only on those who are clearly shown to be wrongdoers.

Although no cases directly on point appear in Michigan, the shifting of the burden of disproving causation once defendant's wrongful conduct has been established appears in other contexts in Michigan law. In *Snider* v *Bob Thibodeau Ford, Inc,* 42 Mich App 708; 202 NW2d 727 (1972), for example, a consumer brought an action against both the manufacturer of his automobile and the dealer who had repaired the brakes which allegedly failed and caused his accident. The trial court in that case directed a verdict for the manufacturer (Ford), and plaintiff appealed. Rejecting Ford's argument that the directed verdict was proper because plaintiff's proofs were insufficient to show which defendant was responsible for the defect, if any, this Court said:

> "Were a jury to decide that the wrong to Snider had been established, the question to which of two possible tortfeasors—Ford or Thibodeau—liability should be assigned does not pose an issue of conjectural cause.
>
> "True, the burden of proving which of two possible wrongdoers is responsible is generally assigned to

> the plaintiff. The courts have, however, shown a willingness to consider special circumstances when allocating the burden of proof. This accords with the general view that the placing of that burden is 'merely a question of policy and fairness based on experience in the different situations'." 42 Mich App, at 718. (Footnote omitted.)

In *Holloway* v *General Motors* (On rehearing), 403 Mich 614; 271 NW2d 777 (1978), the Supreme Court held that plaintiff need not show the precise nature of the defect in defendant's product, so long as he carried his burden of establishing by a preponderance of the evidence that some defect attributable to defendant caused his injury, saying in a footnote:

> "In a somewhat analogous situation, the rule is that a plaintiff need not prove which person among alternative negligent tortfeasors caused his injury. See *Summers* v *Tice*, 33 Cal 2d 80; 199 P2d 1 (1948); Prosser, *supra* § 41, pp 243-44." *Holloway, supra*, fn 15, at 625.

Also instructive is the analysis expressed in *Maddux* v *Donaldson*, 362 Mich 425; 108 NW2d 33; 100 ALR2d 1 (1961), involving successive automobile collisions. The Court held that where plaintiff was unable to prove what portion of the damages were caused by each collision because of the circumstances of the accident, the burden of uncertainty should fall on the wrongdoers, who would be jointly and severally liable for all plaintiff's damages.

> "Is it better, as we asked heretofore, that a plaintiff, injured through no fault of his own, take nothing, rather than that a tort-feasor pay no more than his theoretical share of the damages accruing out of a confused situation which his wrong has helped to create?" *Maddux, supra*, at 435.

The Court answered the question thus posed by holding that, if injustice is inevitable, the burden should fall on the wrongdoer rather than on the innocent plaintiff. With this conclusion we agree.[5]

In the case before us, as in *Maddux, supra,* the problem is essentially one of apportionment of damages among proven wrongdoers. Plaintiffs must establish that they suffered a certain amount of damages at the hands of defendants, all of whom are tortfeasors. Should plaintiffs succeed in establishing that defendants are alternatively liable for this amount of damages, defendants are left to apportion the damages among themselves. Each defendant is free to present proofs absolving itself from liability as to any particular plaintiff or as to all plaintiffs. Defendants are also free to implead any third party whom they believe liable for all or part of the damages.

Plaintiffs in the case at bar bear a heavy, perhaps (as defendants contend) an insuperable, burden of proof, one made even more difficult by the number of defendants and by the length of time between the ingestion of the allegedly defective drug and the appearance of the damages allegedly caused thereby. They must establish by a preponderance of the evidence that each defendant breached its duty of care in producing the product, that the harm to each plaintiff was the result of ingestion of DES by her mother, and that one or more of the named defendants manufactured the DES so ingested.[6] Each plaintiff must carry her burden as to these defendants in order to recover. Should plaintiffs fail to carry their burden as to any or all defendants, they will suffer the consequences. We will not add to plaintiffs' burden by requiring them to apportion damages among the wrongdoers in order to recover.

In so holding, we adopt no new theory of law, despite the urging of plaintiffs that we adopt the "enterprise liability" theory of products liability.[7] We simply follow precedent established by the courts of Michigan and other states in finding that the trial court imposed too heavy a burden on plaintiffs in requiring them to plead more facts than are necessary to state a cause of action in products liability. Accord, *Sindell* v *Abbott Laboratories*, 85 Cal App 3d 1; 149 Cal Rptr 138 (1978). *Cf. McCreery* v *Eli Lilly & Co*, 87 Cal App 3d 77; 150 Cal Rptr 730 (1978).

Reversed and remanded for further proceedings consistent with this opinion.

1. Defendants assert in their brief that only diethylstilbestrol is properly denominated DES, the other compounds being chemically distinct from DES. We express no opinion on the similarities or differences among the various substances, but simply adopt the designation "DES" for convenience.

2. The other classes are: vicarious liability; common duty; concurrent causation of a single, indivisible result, which neither would have caused alone; concurrent causation of a single, indivisible result, which either would have caused alone; successive injuries; damage of the same kind, which it is difficult to apportion; and acts innocent in themselves which together cause damage. Prosser, *Joint Torts and Several Liability*, 25 Cal L Rev 413, 429-442 (1937).

3. See analysis in Sheiner, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L Rev 963, 978-995 (1978).

4. For an excellent discussion of the proof problems which are likely to be presented in this case, see Sheiner, *supra* note 3, 983-985.

5. Defendants seek to distinguish prior alternative liability cases by reason of the fact that the tortious acts occurred within a brief time span. We find this argument unpersuasive. It hardly comports with the notions of fairness which underly the adoption of joint and several liability for independent tortfeasors to hold that a tortfeasor who continues his wrongful conduct over a period of years will be absolved of responsibility for his acts as a reward for his persistence in wrongdoing.

6. Those plaintiffs who believe they are able to identify the defendant who injured them may wish to take the less perilous route of pursuing their cause of action against a sole tortfeasor rather than seeking to establish the alternative liability of all defendants. If so, they will no doubt seek to amend their pleadings accordingly. Those who have already amended their complaint to allege a sole tortfeasor may either amend to allege joint and alternative liability or stand on the most recent amendment.

7. See Sheiner, *supra* note 3, for a discussion of this proposed theory.

STATE OF MICHIGAN
COURT OF APPEALS

No. 77-3421

GAIL ABEL, et al,
Plaintiffs-Appellants,

-v-

ELI LILLY AND COMPANY, ABBOT LABORATORIES, THE BLUE LINE CHEMICAL COMPANY, BURROUGHS WELLCOME COMPANY, CENTRAL PHARMACAL COMPANY, COLE PHARMACAL COMPANY, KREMERS-URBAN COMPANY, McNEIL LABORATORIES, INC., MERCK, SHARPE & COHME, REXALL DRUG COMPANY, WILLIAM J. RORER, INC., S.J. TUTAG AND COMPANY, SCHERING CORPORATION, E.R. SQUIBB AND SONS, INC., UPJOHN COMPANY AND VALE CHEMICAL COMPANY,
Defendants-Appellees.

Moore, J dissent

This is a multiple plaintiffs, drug injury, liability action. On September 17, 1974, this suit was commenced by several plaintiffs seeking individual recovery charging numerous drug manufacturer defendants, jointly or collectively, on an industry-wide basis termed "enterprise liability", with negligent testing of a drug called DES, (synthetic estrogen, etc.), and with promoting and distributing DES for the use of pregnant women, and that some defendants had knowledge, or imputed knowledge, of its dangerous qualities, and failed to warn the consumers of dangerous side effects.

Plaintiffs claim to have been injured at conception or birth, through their respective mothers having ingested

DES acquired under the generic drug marketing system, participated in by defendants.

Plaintiffs' pleadings assert:

"a. That all of the defendants named herein have manufactured pharmaceutical preparations containing dienestrol, diethylstilbestrol and diethylstilbestrol diproprionate, from the late 1940's through the early 1960's and promoted them with the intention that these drugs be prescribed by the medical profession for the purpose of preserving and/or saving the lives of the unborn children (fetuses) of the pregnant mothers to whom the drugs were administered.

"b. That all of the female plaintiffs named herein were in the fetal stage when their mothers took the drug.

"c. That all of the defendants actively promoted these drug preparations to the medical profession and in so doing represented to the medical profession that these drugs were both safe and effective in preserving the lives of the unborn children (the plaintiffs) of the mothers to whom the drugs were administered.

"d. That in fact, there was no reasonable basis for claiming that these drug preparations were effective in preventing miscarriage of unborn children.

"e. That the defendants named herein constitute all of the known manufacturers of stilbene derivatives who promoted, in Michigan, said drugs to the medical profession for use in pregnancy during the period in controversy: to wit, 1947 to 1964.

"f. That the promotion of the stilbene derivatives for use in pregnancy by one or more of the defendants named herein caused the injuries suffered by each of the plaintiffs.

"g. That some of the plaintiffs will be unable to identify the specific defendant that manufactured the injury-producing drug.

"All defendants participated in a generic promotional scheme which has effectively concealed, in many cases, the identity of any specific manufacturer.

"The defendants are jointly and severally responsible as they caused the injuries alleged in this complaint so all defendants are hereby joined as indispensable parties to this lawsuit."

The plaintiffs claim that two decades more or less have elapsed since ingestation and that records have been lost and that because they are innocent parties the burden of certain proofs, being more available to the guilty defendants as a group of manufacturers jointly interested or participating in promotion and sale of the generic drug, justice requires the shifting of the burden of proofs of some matters such as defendants activities, etc., from the plaintiffs to the defendants.

Eventually by pleadings and by stipulation between counsel, the many plaintiffs were listed and divided into two classes: The first, those who believed they could identify the defendants responsible; and, the second, those plaintiffs who admitted they could not so identify any specific defendant responsible.

The defendants moved for summary judgment on December 23, 1974 for failure to state a claim upon which relief could be granted as against the second class of plaintiffs. Specifically, the defendants contended that

I. Partial Summary Judgment should be granted pursuant to GCR 1963, 117.2(1) against all plaintiffs who alleged they were unable to identify the manufacturer of the

drug because they failed to state a claim upon which relief could be granted.

II. Partial Summary Judgment should be granted pursuant to GCR 1963, 117.2(1) because plaintiffs attempted to assert collective, industry-wide liability as a basis to circumvent the essential "manufacturer identification" element of their products liability actions, and failed to state any cause of action cognizable under the law of Michigan.

The trial court on March 10, 1975 dismissed the defendants' motion, without prejudice, concluding that in view of the enormity and complexity of the cases, the plaintiffs were entitled to an opportunity for further discovery. Further discovery depositions were taken.

Thereafter, on February 1, 1977, the defendants filed their second motion for partial summary judgment, asserting that the summary judgment should be granted against all plaintiffs who were still unable to identify the manufacturer of the drug which causes their injury and contending that the plaintiffs' so called "collective liability theory" did not state a cause of action cognizable under the laws of Michigan; and, also, that there was no genuine issue as to any material fact showing, or tending to show, that defendants engaged in a conspiracy or unlawful concert of action. This motion was supported by the affidavit of Dr. Jerome M. Maas.

Dr. Maas, a former employee of the defendant, Eli Lilly Company, stated that during the relevant years of 1950-1964, over 300 manufacturers of the four types of synthetic estrogen, involved in this suit were listed in standard medical references as offering these drugs for sale to pharmacies.

Plaintiffs introduced affidavits of pharmacists Howard Mordue and Louis M. Weiss, who stated that the listed de-

fendants were prominent among those whose products were used to fill prescriptions for DES in Michigan during the period in question.

On May 16, 1977, the trial court made findings by opinion placed on the record. The court granted the defendants' motion for summary judgment as to the plaintiffs who could not identify the manufacturer on the ground that they failed to state a claim upon which relief could be based. The trial court also rejected the so-called "collective liability" theory as to all plaintiffs. On August 25, 1977, Judge Roumell entered a final order granting the defendants' motion for partial summary judgment.[1]

On October 6, 1977, both the plaintiffs and the defendants filed separate bypass applications with the Michigan Supreme Court which were denied. One hundred eighty-two plaintiffs now have appealed as of right.

The issues involved are these: (1) Where certain of the plaintiffs are unable to identify the particular tortfeasor(s) responsible for the injury of each plaintiff, does Michigan law allow the plaintiffs to maintain their products liability action by shifting the burden of proof (called Burden of Uncertainty) to the defendants? (II) Are the defendants jointly liable under a theory called "Group Enterprise Liability" or "Collective Group Liability" for negligently marketing an unsafe drug without adequate testing, if they acted in concert to market and promote the use of DES in Michigan for use during pregnancy?

I would hold that the trial court was correct in its decision. In this case, the plaintiffs are requesting three drastic major changes in Michigan law, which are (1) fallacious in theory, (2) wrong in law, and (3) constitute uncalled-for judicial legislation. These changes should be addressed to legislative action not the appellate courts.

I.

WHERE CERTAIN OF THE PLAINTIFFS ARE UNABLE TO IDENTIFY THE PARTICULAR TORTFEASOR(S) RESPONSIBLE FOR THE INJURY OF EACH PLAINTIFF, DOES MICHIGAN LAW ALLOW THE PLAINTIFFS TO MAINTAIN THEIR PRODUCTS LIABILITY ACTION BY SHIFTING THE BURDEN OF PROOF (CALLED BURDEN OF UNCERTAINTY) TO THE DEFENDANTS?

Plaintiffs contend that the drug companies promoted DES in directing their advertising and promotional efforts at the doctors and pharmacists rather than at the ultimate consumers; that DES was sold as a generic drug so the choice of manufacturer resided with the pharmacist; that even the pharmacists may have been unaware of the identity of the actual manufacturer, since drugs could be labeled with the name of the repackager or distributor; that even those pharmacists who knew the identity of the manufacturer no longer have records of the drugs dispensed to the plaintiffs' mothers; that such marketing system was far different from that usually present in a products liability action which appeals to the ultimate consumer rather than to intermediaries; and that this justified shifting the "burden of uncertainty" to the tortfeasors.

Plaintiffs thus argue for a new type of proof; namely, that where uncertainty exists as to the amount of damages or the individual responsibility of each tortfeasor, the risk of uncertainty shifts to the defendant, especially where his wrong has helped engender the confusion; that this doctrine has been used in anti-trust litigation, in multiple automobile collisions, in hunting accident cases, and in air and water pollution cases; that it is unfair to let the wrongdoers go free just because the injured party cannot prove the

specific share of harm done by each of them; that case law requires shifting the burden even where there is no "conscious concert" of action on the part of the tortfeasors if the injured parties cannot sustain the burden of proof.

Defendants contend that the trial court correctly decided the defendants' motion for summary judgment as to those plaintiffs who were unable to identify the alleged injury-causing drug or its manufacturer; that it is fundamental in any Michigan products liability suit that the plaintiff be able to identify the particular product involved and the manufacturer or seller of this product; that a plaintiff must prove a defect or negligence or a warranty breach attributable to at least one or more specific manufacturers and causal connection between that defect, negligence or breach of warranty, and the injury or damage of which he complains, in order to recover from the manufacturer or a group of manufacturers of the defective product.

Plaintiff's contentions are untenable because:

First, they call for strict liability in product liability cases namely without proof of fault, which is not now Michigan law.

Second, they call for group liability of parties unrelated, except as in enterprise, business, or profession, not necessarily joint tortfeasors, without proof of fault. This is not Michigan law.

Third, they call for a reversal of many well established decisions of Michigan's tort law presently requiring (a) identification of the defendant, (b) tortious activity or behavior of the defendant and, (c) proof of causal connection with resultant damage thereby.

It should always be remembered that stability of law is a basic, precious judicial necessity, without which con-

fusion reigns. Judicial legislation exceeds judicial authority and does great injury to our "separation of powers" doctrine.

As to the plaintiffs' contentions I conclude as follows: There are only two theories of recovery for product liability which are recognized in Michigan: negligence and warranty. *Johnson* v *Chrysler Corp,* 74 Mich App 532, 254 NW2d 569 (1977), *lv den,* 400 Mich 861 (1977). Strict liability is not recognized. Plaintiff must prove that the defendant has supplied a defective product, and that this defect has caused injury to the plaintiff.

Regardless of the theory upon which liability is predicated, whether negligence or breach of warranty, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product. The matter of identification is inherent in every products liability action. 51 ALR 1344, 1349.

In a similar case, *Gray* v *United States,* 445 F Supp 337, 338 (SD Texas, 1978), the plaintiff sued Eli Lilly Drug Company and the government for her injuries caused by the DES ingested by her mother during pregnancy. The Texas District Court upheld summary judgment in favor of the defendant drug company because the plaintiff was unable to identify the manufacturer of the DES taken by her mother.

In *Summers* v *Tice,* 199 P2d 1, 5 ALR2d 91 (Cal, 1948), the plaintiff was struck in the eye by a shotgun pellet when two defendants almost simultaneously fired their guns in his direction. The firing of the guns was tortious. There was no evidence as to which defendant fired the shot which injured the plaintiff. There, the Court decided that the defendants should not be exonerated from liability for their negligence, whether it was

deemed that they acted independently or in concert. The Court held that *under* the circumstances presented, the defendants were *jointly and severally liable,* and the burden of proof shifted to each of the defendants to absolve himself of liability, so the plaintiff was relieved of the duty of apportioning his injury to either one of the defendants.

In *Meier* v *Holt,* 347 Mich 430, 80 NW2d 207 (1956) the plaintiff auto driver could not prove which portion of his injury was caused by each of the two defendants' automobiles and the court stated that the *burden of apportioning the damages* should be shifted to the defendants.

In these two cases, the plaintiff's injury was caused by one of several persons, whom the plaintiff was unable to identify by any available method *but all of whom were at fault.* Rather than deny him recovery altogether due to the uncertainty of the situation, the Court held it more equitable to let the defendants bear the "burden of the uncertainty" than to preclude an innocent plaintiff from a recovery. A similar conclusion was reached in the collision case of *Maddux* v *Donaldson,* 362 Mich 425, 108 NW2d 33 (1961).

In *Oakwood Homeowners Assn, Inc* v *Ford Motor Co,* 77 Mich App 197, 258 NW2d 475 (1977), *lv den,* 402 Mich 847 (1978), an air pollution case where it was proven that one or more of the defendants caused the pollution but where the plaintiffs did not prove injury and liability as to specific tortfeasors, it was held that the law shifts to defendants the burden of proof as to which tortfeasors were responsible and to what degree, *after proof of liability by plaintiffs.*

However, these cases which shift the burden of proof to the defendant do not involve the problem of iden-

tifying the party who is liable but rather the apportionment of damages, after liability is proven. Each defendant in those Michigan cases did some wrongful act toward the plaintiffs so liability was first determined. The defendants had the burden only of proving the *specific proportion of the injury damages* for which they were liable. The courts decided that it would be easier and more equitable *after liability has been proven,* for the defendants to determine their own *degree of culpability* than to deny the plaintiff a recovery. This is the law in Michigan.

So here, in the case at bar, the basic issue has to do *with liability* by identifying the particular wrongdoer(s) rather than apportioning the damages. None of these Michigan cases has shifted the burden of proof of "some" negligence to some of the defendants. The only "shifting" allowed has been as to some damages division after negligence has been proven.

The only possible Michigan support for shifting of the burden of proof is the language of *Synder* v *Thibodeau Ford Inc,* 42 Mich App 708, 202 NW2d 727 (1972):

> "True, the burden of proving which of two possible wrongdoers is responsible generally assigned to the plaintiff. The courts have, however, shown a willingness to consider special circumstances when allocating the burden of proof. This accords with the general view that the placing of that burden is 'merely a question of policy and fairness based on experience in the different situations' ".

However, this language was merely dicta.

The Michigan case law is clear that plaintiff must prove 1) the defendant to be the manufacturer, 2) that the product was defective, and 3) that injury resulted

therefrom. *Smith* v *Squibb*, 69 Mich App 375, 245 NW2d 52 (1976); *Piercefield* v *Remington Arms Inc*, 375 Mich 85, 133 NW2d 129 (1965); *Cova* v *Harley Davidson*, 26 Mich App 602, 182 NW2d 800 (1970).

Michigan case law as to successive or near simultaneous tortfeasors is that each tortfeasor is responsible for his own wrong, taking the injured person as found. However, when proof of harm is uncertain, the defendants are both liable jointly and severally for the total wrong unless the jury finds otherwise based upon the proofs. *Synder, supra; Meier* v *Holt, supra, Maddux* v *Donaldson, supra.*

All Michigan cases require plaintiffs to prove liability.

Restatement of Torts 2d, pp 315-316 states:

> "For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he
>
> "(a) does a tortious act in concert with the other or pursuant to a common design with him, or
>
> "(b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or
>
> "(c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person."

This section codifies the rule of *Summers* v *Tice, supra*, p 441. Restatements of Torts 2d.

I conclude the shifting of proofs is only as to degree or percent of damages, after, and only after, liability of at least one defendant acting in concert has been proven.

II.

ARE THE DEFENDANTS JOINTLY LIABLE UNDER A THEORY CALLED "GROUP ENTERPRISE LIABILITY" OR "COLLECTIVE GROUP LIABILITY" FOR NEGLIGENTLY MARKETING AN UNSAFE DRUG WITHOUT ADEQUATE TESTING, IF THEY ACTED IN CONCERT TO MARKET AND PROMOTE THE USE OF DES IN MICHIGAN FOR USE DURING PREGNANCY?

Appellants argue that Michigan should adopt the "enterprise liability" theory to hold the entire group of defendants who marketed DES without adequate testing liable for the injuries caused by the drugs without proof of fault of any one defendant. This doctrine, which was recognized in a series of blasting cap cases, does not require proof of a formal joint venture or a conspiracy. Joint control may be established by proof of an explicit agreement, or of parallel behavior supporting an inference of a tacit agreement or cooperation, or thirdly, by proof of independent adherence to an industry-wide standard or custom. The difficulty with this enterprise liability theory lies in the lack of proof of real responsibility of at least one party defendant. Some liability of one defendant must precede drawing in others. For instance if none is identified why should we not conclude none are liable? Further, to shift proof of damages to defendants requires proof of some liability and this means identification of at least one party at fault. Otherwise, proof of damage becomes the substitute for proof of liability. When no one defendant-manufacturer can be identified, the existence of industry-wide standards or practices may not be substituted to support a finding of fault. The concept of "enterprise liability," although not essentially different from that of *Summers* v *Tice,* is a

broader remedy than simply shifting the burden of uncertainty of damage allocation to ascertained tortfeasors. We cannot promiscuously make an entire industry liable without some liability being first established against someone.

There is no Michigan precedent to support the plaintiffs' theory of joint or collective industry-wide liability. The activities alleged by the plaintiffs in their 14th amended complaint fall short of setting forth a cause of action for conspiracy, and plaintiffs' counsel indicated during oral argument that the conspiracy claims were abandoned. Any concerted action alleged by the plaintiffs was only in response to the mandate and requirements of federal law and FDA procedures. Any company which manufactures DES must use the same formula and official name or be subject to penalties under 21 USC § 352(e).

In the case at bar, identification information certainly did exist at one time, and its present unavailability is not due to any action by the defendants herein, but is due to the passage of time. To accept the plaintiffs' theory of enterprise liability would result in a penalty for conduct which was undertaken in compliance with federal law concerning prescription drugs.

The "strict liability" rule is not recognized in Michigan. Instead, liability must be shown to arise from warranty express or implied, or from negligence.

Michigan law does not suport "collective liability." *The fact of injury alone does not establish a legal duty* by society toward the injured party to provide compensation. Every injury is not legally compensable. Injury alone does not justify imposing liability on one manufacturer for injuries caused by another manufacturer of the same or similar product.

Even where there is a naked, constitutionally sound policy established legislatively, like no-fault insurance, the constitutional validity fails unless there is reasonableness and insurable or actionable protection available to the group.

There must be some fault directly proven against the manufacturer or some activity done or position taken to create liability, even through a member of a group.

To say it another way, absent legislative action and legal responsibility springing therefrom, one may not be obligated for the fault of a fellow lawyer, or doctor, or engineer, or a drug manufacturer. Both due process and equal protection so protects all of us.

The collective liabiilty theory violates due process and equal protection guarantees of the Constitution. The courts cannot create a remedy which is in violation of liability law.

The naked collective liability theory would result in taking of the property of all of the defendants in order to pay for harm which may have been caused by the conduct of only one defendant or even by one who is not a party to this lawsuit, and over whom the defendants have no control, or with whom they have no meaningful contact. Due process requires that state action which deprives a person of his property must have a rational basis, it must not be arbitrary. Naked collective liability relieving the plaintiffs of the burden of proving that these defendants are certain specific defendants caused or participated in causing the harm would also deny certain of the defendants themselves equal protection.

The trial court's grant of summary judgment should be affirmed in favor of all non-identified defendants as against those plaintiffs who have alleged that they can-

not identify the manufacturer of the drug which allegedly caused their injury.

The trial court properly interpreted Michigan products liability law, properly declined to adopt the "enterprise liability" theory and properly dismissed the suits by the plaintiffs who could not identify any responsible pharmaceutical defendant.

Decision of the trial court should be affirmed.

FOOTNOTE:

1. That order read *inter alia*:

"Plaintiffs seek to hold the defendants responsible on a theory identified alternatively as 'joint liability theory' or 'enterprise liability theory', 'synthetic drug industry liability theory', or 'industry wide liability theory'. The basis and concept for recovery is predicated upon the notion that all manufacturers involved here must share equally the burden of defense and the payment of any recovery made in damages.

"The Court holds that plaintiffs have failed as a matter of law to state a claim upon which relief may be granted.

> "'* * * [I]t is necessary to show that the defendant actually manufactured, compounded, or sold the drug or medicine in question. Annotation, Liability of Manufacturer or Seller for Injury Caused by Drug or Medicine Sold, 72 ALR2d 301, 338 (1961).
>
> "'* * * [T]here must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product, and this rule is supported in all of the cases examined in this annotation. Annotation, Products Liability: Necessity and Sufficiency of Identification of Defendant as Manufacturer or Seller of Product Alleged to Have Caused Injury, 51 ALR3d 1344, 1349 (1973).
>
> "'* * * 1 Hursh & Bailey, American Law of Products Liability 2d, § 1:41 (1974); accord, 63 Am Jur 2d, Products Liability, § 5, at 12.
>
> "'* * * *Wetzel* v *Eaton Corp*, 62 F.R.D. 22 (D. Minn. 1973); *Symons* v *Mueller Co*, 526 F2d 13 (10th Cir. 1975).
>
> * * *
>
> "'In Michigan, it is clear that a products liability plaintiff must identify the product allegedly causing injury and attribute that product to the defendant manufacturer. *Smith* v *E. R. Squibb & Sons, Inc*, 69 Mich App 375, 245 NW2d 52 (1976); *Losinski* v *Ford Motor Co*, 43 Mich App 114, 118, 204 NW2d 40, 52 (1972); *Cova* v *Harley Davidson Motor Co*, 26 Mich App 602, 609, 182 NW2d 800, 804 (1970). In *Piercefield* v *Remington Arms Co*, 375 Mich 85, 133 NW2d 129 (1965), the court summarized the "identification" requirement as follows:
>
> "'"[A] plaintiff . . . must prove a defect attributable to the manufacturer and causal connection between that defect and the injury or damage of which he complains. When able to do that, then and only then may be recover against the manufacturer of the defective product."' 375 Mich., at 99, 133 NW2d, at 135.

"Pursuant to Michigan law, the failure and inability of those plaintiffs to so identify the manufacturer and to identify the alleged injury-causing product means that those plaintiffs have failed to state a claim upon which relief can be granted within the meaning of Michigan, GCR 117.2(1)."

E. Order pursuant to Opinion of the Michigan Court of Appeals, dated March 11, 1980

STATE OF MICHIGAN
COURT OF APPEALS

REMITTITUR OF RECORD

This cause having been brought to this Court by appeal, and after due consideration the Court having issued its opinion;

IT IS NOW ORDERED by the Court that this cause be and the same is hereby remanded to the trial court or tribunal for entry of judgment or any other necessary action in accordance with the opinion attached hereto and incorporated as part of this order, and for notice by the clerk of the lower court or tribunal to counsel as required by GCR 1963, 812.11.

STATE OF MICHIGAN—ss.

I, Ronald L. Dzierbicki, Chief Clerk of the Court of Appeals of the State of Michigan, do hereby certify that the foregoing is a true and correct copy of an order entered in said Court in said cause; that I have compared the same with the original, and that it is a true transcript therefrom, and the whole of said original order.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Court of Appeals at Lansing, this March 11, 1980.

/s/ Ronald L. Dzierbicki
Chief Clerk

F. Defendants' Joint Brief in Support of Joint Motion for Summary Judgment, Circuit Court for the County of Wayne (excerpt p. 37)

* * *

[37] The public policy of the State of Michigan does not sanction or endorse the taking of one person's property, for the benefit of another, without a "definite basis" for that reallocation being established in a court of law. Plaintiffs' inability in the instant case to establish the identity of the wrongdoer causing injury, makes it patently impossible for plaintiffs to ever establish the liability of any defendant on a "definite basis." Further, it seems clear that plaintiffs' theories of industry-wide liability contravene defendants' constitutional rights as preserved for them by the Fourteenth and Fifth Amendment to the United States Constitution, and by both Article I, Section 17, and Article X, Section 2, of the Constitution of the State of Michigan.

The United States Constitution, the Michigan Constitution and the public policy of the State of Michigan all preclude imposing the type of industry-wide liability urged by the plaintiffs in *Abel*. For these additional reasons, the industry-wide liability complaints asserted by the plaintiffs in this lawsuit, fail to state a claim cognizable under the law of Michigan, upon which relief can be granted. Therefore, summary judgment should be granted defendants as to these claims, pursuant to GCR 1963, 117.2(1), as a matter of law.

G. Defendants' Joint Reply Brief on Summary Judgment, Circuit Court for the County of Wayne (excerpt pp. 47-51)

[47]

IV.

Because Plaintiffs' Claims Contravene Constitutional Protections Afforded Defendants, Plaintiffs Do Not State Causes Of Action Cognizable Under The Law Of Michigan, And Defendants Are Entitled To Summary Judgment As A Matter Of Law.

Not only is there no basis in the common law, the precedents or statutes of Michigan, or the statutes of the United States for either the industry-wide enterprise theory or the generic distribution theory, but the adoption of any such theory is prohibited by the substantive and procedural due process provisions of the Fourteenth Amendment. That Amendment provides: "[N]or shall any State deprive any person of life, liberty, or property, without due process of law . . . ."

Relying upon *Maddux* v. *Donaldson*, 362 Mich. 425, 108 N.W.2d 33 (1961), plaintiffs in their Brief in Opposition argue that there is no constitutional objection to the imposition of joint and several liability in this case. *Maddux* simply does not support such a broad proposition.[15]

---

15. At issue in that case was whether a plaintiff receiving a single indivisible set of injuries in an automobile chain collision had to establish the origin of each of his injuries. Defendants have repeatedly demonstrated that this case is unlike the chain collision cases and the hunters cases and the other precedents utilized by plaintiffs. Plaintiffs call for an extravagant expansion and application of concepts developed in a completely different context.

Plaintiffs also argue, again alluding to *Maddux*, that without these theories they will be left remediless and that this is inequitable. This argument totally ignores the effect of plaintiffs' proposed theories on the defendants. In *Rees* v. *Watertown*, 86 U.S. (19 Wall.) 107 (1873), the Supreme Court, relying upon the Magna Carta and the due process clause, stated: "A court of equity cannot, by avowing that there is a right but no remedy known to the law, create a remedy in violation of law, or even without the authority of law." *Id.* at 122.

What is really at issue in this case is whether there are limits to the burdens and liabilities which this Court can [48] impose in the exercise of State power. The doctrine of substantive due process remains a bulwark against unreasonable governmental power. It is a principle, rooted in the traditions of our people, which can be traced from the earliest days of English law up to recent decisions such as *Roe* v. *Wade*, 410 U.S. 113 (1973).

A judicial decision by a State Court is subject to the constraints of substantive due process. *See American Ry. Exp.* v. *Kentucky*, 273 U.S. 269 (1927); *Prudential Ins. Co.* v. *Cheek*, 259 U.S. 530 (1922); *Patterson* v. *Colorado*, 205 U.S. 454 (1907); *Backus* v. *Port St. Union Depot Co.*, 169 U.S. 557 (1898); *Chicago, B. & O. R.R. v. Chicago*, 166 U.S. 226 (1897). If plaintiffs' theories are accepted by this Court as a basis for common law liability, such a holding will violate the Fourteenth Amendment. It will amount to taking the property of all the defendants to pay for harm which may have been caused by the product of only one defendant—or very probably by a person not even a party to this lawsuit—and over whom

the defendants had no control and with whom they had no meaningful contact or relationship.[16]

The claim that one is entitled to substantive due process means that the State action which deprives a person of his property must have a rational basis, i.e., the reason may not be [49] so inadequate that a Court will characterize it as arbitrary. *Jeffries* v. *Turkey Run Consol. School Dist.*, 492 F.2d 1, 3-4 (7th Cir. 1974) (opinion per Justice, then Judge, Stevens). When we realize that plaintiffs seek to have judgments rendered against but a fraction of those pharmaceutical firms which manufactured DES and the other two products over a 17 year period, the arbitrariness of their position is manifest. The alleged generic distribution scheme, as described by plaintiffs, by its very nature had to include all those hundreds of pharmaceutical firms which manufactured the products during the years in question. Nothing could be more arbitrary than to exclude from liability those whom plain-

---

16. Plaintiffs' proposed theories are a fundamentally unfair form of vicarious liability without the factors necessary to make them constitutionally reasonable. The Supreme Court has considered several cases which provide guidance for analysis of the industry-wide theory. *See Atlantic Coast Line R.R.* v. *Riverside Mills*, 319 U.S. 186 (1911) (principal-agent); *New York Cent. R.R.* v. *White*, 243 U.S. 188 (1917) ("alter ego"); *Eiger* v. *Garrity*, 246 U.S. 97 (1918) (principal-agent); *Van Oster* v. *Kansas*, 272 U.S. 465 (1926) (bailor-bailee); *Young* v. *Masci*, 289 U.S. 253 (1933) (same).

In each of these cases, a close contractual or other principal and agent relationship existed between the vicariously liable defendant and the active tortfeasor and was therefore found to be a constitutionally reasonable and indispensable standard for the imposition of vicarious liability. No such relationship, close or otherwise, among defendants may be found to have existed at the times relevant to the case at bar and, indeed, plaintiffs' theory is that no relationship or concert of action is even necessary but rather independent negligence by many, only one of which in fact caused injury is sufficient for joint or vicarious liability. Clearly this theory violates the constitutional predicate of these decisions.

tiffs themselves must say are part of the unique scheme through which they were injured.[17]

Moreover, the defendants will be deprived of procedural due process if the plaintiffs' theories are accepted. Due process requires that there be "a meaningful opportunity to be heard" and that this opportunity to be heard "must be protected against denial by particular laws that operate to jeopardize it for particular individuals." *Boddie* v. *Connecticut,* 401 U.S. 371, 377, 379-80 (1971). *Accord, Goldberg* v. *Kelly,* 397 U.S. 254, 268-69 (1970). "Due process requires that there be an opportunity to present every available defense." *Lindsey* v. *Normet,* 405 U.S. 56, 66 (1972). Plaintiffs' theories require each defendant to prove its lack of involvement with a particular plaintiff or the involvement of another defendant in order to avoid liability. This is "an unrealistic option", *Goldberg* v. *Kelly, supra,* 397 U.S. at 269, in light of the unavailability of [50] the documents and records which might have been used in such a defense.[18]

---

17. As to plaintiffs' attempt to limit the "culpable defendants" to those who did business in Michigan, that attempted classification does not meet the constitutional test. First, defendants have demonstrated that the classification just is not accurate. Second, any limited geographical classification is *ipso facto* arbitrary w en the "scheme" itself is not said to have had any geographical limitation. Third, it does not appear that all the mothers purchased the products in Michigan, thus the classification has no relation at all to the geographical area in which plaintiffs seek to limit liability.

18. The Fourteenth Amendment guarantees not only "due process of law" but also "equal protection of the laws". Both of these constitutional protections will be violated under plaintiffs' theories. Defendants generally are entitled to have plaintiffs prove they caused the injuries. Relieving plaintiffs of that burden is a denial of equal protection and substantive due process in that there is no rational basis for the separate classification of the defendants here. The only rationale for the theory and shift in burden of proof is that plaintiffs will then be compensated. Since this rationale exists in all tort cases, the separate

(Continued on following page)

The guarantees of "due process of law" and "equal protection of the laws" contained in the Fourteenth Amendment extend to corporations. *See, e.g., Louis K. Liggett Co.* v. *Baldridge,* 278 U.S. 105, 111 (1928); *Smyth* v. *Ames,* 169 U.S. 466, 522 (1898). Corporations are "persons" fully entitled to complete and adequate protection of their constitutional rights:

> The rights and securities guaranteed to persons by that instrument cannot be disregarded in respect to these artificial entities called corporations any more than they can be in respect to the individuals who are the equitable owners of the property belonging to such corporations. A State has no more power to deny corporations the equal protection of the law than it has to individual citizens. [*Gulf, C. & S. F. Ry.* v. *Ellis,* 165 U.S. 150, 154 (1897).]

This is not a case in which "property rights" and privilege are pitted against the individual rights of the plaintiffs.

> [T]he dichotomy between personal liberties and property rights is a false one. Property does not have rights. People have rights. The right to enjoy property without unlawful deprivation, no less than the right to speak or the right to travel, is in truth a

---

Footnote continued—

classification of these defendants is arbitrary and capricious. There is no justification for tort liability here that is not present in any other tort case. *See Wright* v. *Staff Jennings, Inc.,* 405 P.2d 624, 628 (Ore.Sup.Ct. 1965). Furthermore, the classification of these defendants "impinges upon a fundamental right explicitly [and] implicitly protected by the Constitution, thereby requiring strict judicial scrutiny" for equal protection purposes. *San Antonio School Dist.* v. *Rodriguez,* 411 U.S. 1, 17 (1973). There is no compelling state interest to justify imposition of liability on these defendants and the deprivation of their property.

"personal" right. . . . [*Lynch* v. *Household Finance Corp.*, 405 U.S. 538, 552 (1972).]

[51] Due process may be summed up in one word: "fairness". *Fern* v. *Thorp Public School*, 532 F.2d 1120, 1133 (7th Cir. 1976). The attempted deprivation of defendants' property, on the facts of this case, through the enterprise or generic distribution theories is fundamentally unfair.

H. Defendants' Brief on Appeal to Michigan Court of Appeals (excerpt pp. 46, 120-124)

* * *[14]

[120]

V. PLAINTIFFS' THEORIES OF JOINT OR COLLECTIVE, INDUSTRY-WIDE LIABILITY ARE UNCONSTITUTIONAL.

Not only are plaintiffs' theories of liability based on an alleged industry-wide, generic marketing system without support in Michigan precedent and contrary to sound public policy, but the adoption of such theories by this Court is prohibited by the due process and equal protection guarantees of the Fourteenth Amendment. That Amendment provides: "[N]or shall any State deprive any person of life, liberty, or property, without due process of law, nor deny to any person within its jurisdiction the equal protection of the laws." In short, because plaintiffs' claims contravene constitutional protections afforded defendants, plaintiffs do not state causes of action cognizable under the law of Michigan, and defendants are entitled to summary judgment as a matter of law.

---

[46] 14. In the United States, these principles arise out of the adoption of the common law system of jurisprudence with its emphasis on the rights of the individual and the protection of property. These principles contrast with the approach taken in non-common law countries where the burden is placed on the defendant to avoid responsibility. *See* Fleming, *The Role of Negligence in Modern Tort Law*, 53 Va. L. Rev. 815 (1967). While there has been a refinement of tort principles during the two centuries of our national existence, the Fourteenth Amendment of the United States Constitution still preserves the right that no person shall be deprived of property without due process of law. Due process requires a "definite basis" for tort liability. *See Goodman* v. *Stafford*, 20 Mich. App. 631, 638, 174 N.W.2d 593, 596 (1969). Without identification of the product and the manufacturer involved in the injury-causing event, there is no "definite basis" for tort liability.

It is constitutionally insufficient to argue that without these theories of liability plaintiffs will be left remediless and that such a result is inequitable. In *Rees* v. *Watertown*, 86 U.S. (19 Wall.) 107 (1873), the Supreme Court, relying upon the Magna Carta and the due process clause, stated: "A court of equity cannot, by avowing that there is a right but no remedy known to the law, create a remedy in violation of law, or even without the authority of law." *Id.* at 122. As will be demonstrated, adoption of plaintiffs' theories will create a remedy in violation of constitutional guarantees.

There is no Michigan precedent for the liability plaintiffs seek to impose. Careful and complete analysis of the public policy interests at stake indicates that such liability should not be imposed, [See Brief, Section IV, *supra*]. What is at issue at this juncture is whether, notwithstanding the lack of support for plaintiffs' theories, there are limits to the burdens and liabilities which a court can impose in the exercise of State power. Those limits are found in the doctrine of substantive due process. The doctrine of substantive due process remains a bulwark against [121] unreasonable governmental power. It is a principle, rooted in the traditions of our people, which can be traced from the earliest days of English law up to recent decisions such as *Roe* v. *Wade*, 410 U.S. 113 (1973).

Judicial decisions by State courts, as well as legislative enactments, are subject to the restraints of substantive due process. *See American Ry. Express Co.* v. *Kentucky*, 273 U.S. 269 (1927); *Prudential Ins. Co.* v. *Cheek*, 259 U.S. 530 (1922); *Patterson* v. *Colorado ex rel. Atty. Gen.*, 205 U.S. 454 (1907); *A. Backus, Jr. & Sons* v. *Fort St. Union Depot Co.*, 169 U.S. 557 (1898); *Chicago,*

B. & Q. R.R. v. *Chicago,* 166 U.S. 226 (1897). If plaintiffs' theories are accepted by this Court as a basis for tort liability, such a holding will violate the Fourteenth Amendment. It will result in taking the property of all the defendants to pay for harm which may have been caused by the product of only one defendant—or very probably by a person not even a party to this lawsuit—and over whom the defendants had no control and with whom they had no meaningful contact or relationship.[58]

The guarantee of substantive due process means that the State action which deprives a person of his property must have a [122] rational basis, that is, the reason may not be so inadequate that a Court will characterize it as arbitrary. *Jeffries* v. *Turkey Run Consol. School Dist.,* 492 F.2d 1, 3-4 (7th Cir. 1974) (opinion by Judge, now Justice, Stevens). The conceptual basis for plaintiffs' theories of liability is succinctly stated at page 51 of their

---

58. Plaintiffs' proposed theories are a fundamentally unfair form of vicarious liability without the factors necessary to make them constitutionally reasonable. The Supreme Court has considered several cases which provide guidance for analysis of the industry-wide theory. *See Atlantic Coast Line R.R.* v. *Riverside Mills,* 219 U.S. 186 (1911) (principal-agent); *New York Cent. R.R.* v. *White,* 243 U.S. 188 (1917) ("alter ego"); *Eiger* v. *Garrity,* 246 U.S. 97 (1918) (principal-agent); *Van Oster* v. *Kansas,* 272 U.S. 465 (1926) (bailor-bailee); *Young* v. *Masci,* 289 U.S. 253 (1933) (same).

In each of these cases, a close contractual or other principal and agent relationship existed between the vicariously liable defendant and the active tortfeasor and was therefore found to be a constitutionally reasonable and indispensable standard for the imposition of vicarious liability. No such relationship, close or otherwise, among defendants may be found to have existed at the times relevant to the case at bar and, indeed, plaintiffs' theory is that no relationship or concert of action is even necessary but rather independent negligence by many, only one of which in fact caused injury is sufficient for joint or vicarious liability. Clearly this theory violates the constitutional predicate of these decisions.

Brief on Appeal: "It is the theoretical potential for causing damages *rather than what was actually done,* which determines liability." (Emphasis added) This reason for tort liability is arbitrary and capricious in the extreme. The theoretical potential for causing damage exists in all persons and all situations. Imposition of liability without proof of the fact that the act of the defendant was the cause of the harm is contrary to long standing Anglo-Saxon legal traditions. *Cf.* 4 W. *Blackstone, Commentaries** 21. Potentially harmful conduct without a causal connection to resulting injury is not a sufficient interference with the rights of others to justify imposition of tort liability. In effect, what plaintiffs' theories do is create a tort consisting solely of the fact of manufacture of DES. This is an unconstitutional deprivation of the right of the defendants to engage in business. It is also an unconstitutional discrimination in that no other manufacturers of products are subjected to such liability.

The Fourteenth Amendment guarantees not only "due process of law" but also "equal protection of the laws." Both of these constitutional protections will be violated under plaintiffs' theories. Defendants generally are entitled to have plaintiffs prove that they caused the injuries. Relieving plaintiffs of that burden is a denial of equal protection and substantive due process in that there is no rational basis for the separate classification of the defendants here. The only rationale for these theories and the [123] shift in the burden of proof is that plaintiffs will then be compensated. Since this rationale exists in all tort cases, the separate classification of these defendants is arbitrary and capricious. There is no justification for tort liability here that is not present

in any other tort case. *See Wights* v. *Staff Jennings, Inc.*, 241 Or. 301, 405 P.2d 624, (1965).[59]

The guarantees of "due process of law" and "equal protection of the laws" contained in the Fourteenth Amendment extend to corporations. *See, e.g., Louis K. Liggett Co.* v. *Baldridge,* 278 U.S. 105, 111 (1928); *Smyth* v. *Ames,* 169 U.S. 466, 522 (1898). Corporations are "persons" fully entitled to complete and adequate protection of their constitutional rights:

> The rights and securities guaranteed to persons by that instrument cannot be disregarded in respect to these artificial entities called corporations any more than they can be in respect to the individuals who are the equitable owners of the property belonging to such corporations. A State has no more power to deny corporations the equal protection of the law than it has to individual citizens. [*Gulf, C. & S. F. Ry. Co.* v. *Ellis,* 165 U.S. 150, 154 (1897).]

This is not a case in which "property rights" and privilege are pitted against the individual rights of the plaintiffs.

> [T]he dichotomy between personal liberties and property rights is a false one. Property does not have rights. People have rights. The right to enjoy prop-

---

59. The classification of these defendants in this manner "impinges upon a fundamental right explicitly [and] implicitly protected by the Constitution, thereby requiring strict judicial scrutiny" for equal protection purposes. *San Antonio School Dist.* v. *Rodriquez,* 411 U.S. 1, 17 (1973). There is no compelling state interest to justify imposition of liability on these defendants and the deprivation of their property. Although it is unusual to conceive of tort liability in terms of "strict scrutiny," the extraordinary nature of the proposed liability validates such an analysis.

> erty without unlawful deprivation, no less than the right to speak or the right to travel, is in truth a "personal" right. . . . [*Lynch* v. *Household Finance Corp.*, 405 U.S. 538, 552 (1972).]

[124] Due process may be summed up in one word: "fairness". *Fern* v. *Thorp Public School*, 532 F.2d 1120, 1133 (7th Cir. 1976). The attempted deprivation of defendants' property, on the facts of this case, through the enterprise or generic distribution theories is fundamentally unfair.

I. Defendants' Brief on Appeal, Supreme Court of Michigan (excerpt pp. 47-49)

* * *

[47]

VI.

THE THEORIES OF LIABILITY ADOPTED BY THE COURT OF APPEALS VIOLATE DEFENDANTS' CONSTITUTIONAL RIGHTS TO PROCEDURAL DUE PROCESS, SUBSTANTIVE DUE PROCESS, EQUAL PROTECTION OF THE LAWS, UNDER THE MICHIGAN AND UNITED STATES CONSTITUTIONS, AND CONTRAVENE THE SUPREMACY AND COMMERCE CLAUSES OF THE UNITED STATES CONSTITUTION.

In shifting to all defendants the burden of disproving causation "because it is impossible to tell which one is responsible" (361a-362a), the Court of Appeals established [48] a mandatory presumption of liability, *County Court of Ulster Co.* v. *Allen*, 442 U.S. 140 (1979), which is so irrational, arbitrary and fundamentally unfair as to be contrary to the constitutional guarantee of procedural due process. *See Speiser* v. *Randall*, 357 U.S. 513, 523-524 (1958); *Western & Atl. R. Co.* v. *Henderson*, 279 U.S. 639, 642 (1929); *Serafin* v. *Serafin*, 67 Mich. App. 517, 523-524, 241 N.W.2d 272, 275 (1976), *aff'd on other grounds*, 401 Mich. 629, 258 N.W.2d 461 (1977); Const 1963, art 1, § 17. Because it cannot "at least be said with substantial assurance that the presumed fact [manufacture of the products taken by a particular plaintiff's mother] is more likely than not to flow from the proved fact [defendants manufactured a synthetic estrogen and plaintiff's mother took someone's synthetic estrogen] on which it is made to

depend," *Leary* v. *United States*, 395 U.S. 6, 36 (1969), the presumption is irrational or arbitrary, and thus is an unconstitutional deprivation of defendants' due process right to be heard, based on rational rules of procedure. U.S. Const, Am XIV; *Boddie* v. *Connecticut*, 401 U.S. 371, 379 (1971); *Jenkins* v. *McKeithen*, 395 U.S. 411, 429 (1969). *See also* U.S. Const, Am V.

It is further a violation of substantive due process to hold these manufacturers liable for an injury on the basis that they manufactured a product which *could* have caused the injury. U.S. Const, Am XIV; *Wolff* v. *McDonnell*, 418 U.S. 539, 557-558 (1974); *Cf. Giaccio* v. *Pennsylvania*, 382 U.S. 399, 403 (1966); *Rees* v. *Watertown*, 86 U.S. (19 Wall.) 107, 122 (1874). *See also* U.S. Const, Am V.

The Court of Appeals' opinion in *Abel* also violates defendants' constitutional rights to equal protection of the law. U.S. Const, Am XIV; Const 1963, art 1, § 2; *Blair* v. *Wayne State University*, 53 Mich. App. 641, 220 N.W.2d [49] 202 (1974); *rev'd per curiam on other grounds*, 393 Mich. 769, 224 N.W.2d 283 (1974); *Reed* v. *Reed*, 404 U.S. 71 (1971); *Smith* v. *Cahoon*, 283 U.S. 553 (1931); *Stanley* v. *Illinois*, 405 U.S. 645, 648, 656 (1972). *See also, Carrington* v. *Rash*, 380 U.S. 89 (1965); *Dunn* v. *Blumstein*, 405 U.S. 330, 349-352 (1972); *Shapiro* v. *Thompson*, 394 U.S. 618 (1969).

The Court of Appeals' opinion creating liability for the marketing of federally approved generic drugs violates the Supremacy Clause of Article VI of the United States Constitution, because it retards, impedes, burdens and otherwise frustrates the full effectiveness of federal law. U.S. Const, art VI, § 2; *McCulloch* v. *Maryland*, 17 U.S. (Wheat.) 316 (1819); *Sola Elec. Co.* v. *Jefferson Elec. Co.*, 317 U.S. 173 (1942); *Perez* v. *Campbell*, 402

U.S. 637, 651-652 (1971); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959); *People* v. *Bricker*, 389 Mich. 524, 208 N.W.2d 172 (1973); *People* v. *Jondreau*, 384 Mich. 539, 185 N.W.2d 375 (1971); *People* v. *Pennington*, 383 Mich. 611, 178 N.W.2d 471 (1970).

The Court of Appeals' opinion also violates the Interstate Commerce Clause of the United States Constitution by erecting barriers to the free flow of commerce. U.S. Const, art I, § 8; *DiSanto* v. *Pennsylvania*, 273 U.S. 34, 43-44 (1927) (Stone, J., dissenting), *majority overruled*, 313 U.S. 109 (1941); *Dean Milk Co.* v. *Madison*, 340 U.S. 349 (1951); *Southern Pacific Co.* v. *Arizona*, 325 U.S. 761 (1945).

Defendants respectfully urge that all of the constitutional violations addressed above would apply with equal or greater force to market share liability.

J. Defendant E. R. Squibb & Sons, Inc.'s Brief in Support of Motion for Rehearing, Supreme Court of Michigan (excerpt pp. 12-43)

ARGUMENT I

THIS COURT'S OPINION SHOULD BE REHEARD SINCE IT ACCOMPLISHES A TAKING OF DEFENDANT'S PROPERTY IN VIOLATION OF DEFENDANT'S RIGHTS TO SUBSTANTIVE DUE PROCESS.

Defendant E. R. Squibb & Sons, Inc. (hereinafter, "Defendant Squibb"), applies for a Rehearing of the February 6, 1984 Opinion of this court for the reason that the adoption of "DES-unique" alternative liability against manufacturers and distributors of diethylstilbestrol (DES), dienestrol, and diethylbestrol dipropionate (DSD) under the provisions of the recent Opinion of this Court deprives Defendant Squibb of due process of law under the Fifth and Fourteenth Amendments to the United States Constitution.

As an initial observation, Defendant Squibb respectfully points out to the Michigan Supreme Court that this Opinion is so riddled with concessions, reservations and distinctions that it is difficult to apprehend why the adoption of alternative liability is a legal thesis whose time has arrived. If the property of Defendant Squibb is to be taken by the state for the benefit of Plaintiffs, it is to be taken in accord with the Opinion of the Michigan Supreme Court, which forthrightly concedes a number of extremely difficult problems relating thereto.

The Opinion of this Court candidly agrees that, unlike the general rule, a majority, viz. 113, of the Plaintiffs in the instant action is wholly unable to prove, or merely even identify, the specific manufacturer of a synthetic estrogen, or indeed, the product itself, allegedly taken by their mothers when Plaintiffs were *in utero*. (Opinion,

pp. 2, 5, 7, 8, and 20) The Court frankly acknowledges that the Plaintiffs seek a way to "circumvent" the traditional tort procedural safeguards generally extended to products liability defendants which require identification of products manufacture, defect, causation, and damages. (Opinion, p. 2) The Court concedes that the doctrine advanced by Plaintiffs in the instant case is ". . . [i]n order to bypass the identification requirement . . . ." (Opinion, p. 2) The Court finds that Defendants have correctly asserted the general rule of the law of products liability, i.e., that the "threshold" requirement of *any* products liability action is the identification of the injury-causing product and its manufacturer, the Court citing with approval *Piercefield* v *Remington Arms Co, Inc,* 375 Mich 85, 98-99; 133 NW2d 129, 134-135 (1965). (Opinion, p. 7)

The Court acknowledges that the backdrop of such universally-accepted legal pleading and proof requirements is primarily a facet of the factual causation element of tort law. (Opinion, p. 7, fn. 8) The legal requirement of "proximate causation" arises out of concern for a defendant's potential civil exposure to damages greatly out of proportion to his acts. If such products liability is not limited by proximate causation, a defendant can be punished to the point of deterrence of performing useful and desirable activity, the Court notes. (Opinion, p. 8, fn. 8) See *Caldwell* v *Fox,* 394 Mich 401, 410; 231 NW2d 46, 50 (1975); Hursh & Baily, *American Law of Products Liability,* 2d, §1.41, p. 125; Annotation, 51 ALR 3d 1344, 1349. Requiring proof that a tortfeasor has, in fact, caused the injury of the plaintiff also reflects ". . . common notions of moral responsibility or blame." (Opinion, p. 9, fn. 8)

Reasoning form *Maddux* v *Donaldson,* 362 Mich 425; 108 NW2d 33 (1961), a case involving *successive* collisions and expostulating a rule of apportioning *damages* in a clear

liability context (Opinion, p. 11), guided by *Benson* v *Ross*, 143 Mich 452; 106 NW 1120 (1906), involving a clearly non-simultaneous shooting of three hunters jointly engaged with a common purpose, considering *Holloway* v *General Motors Corp*, 403 Mich 614; 271 NW2d 777 (1978), whether the automobile manufacturer or dealer should be liable for an "either/or" defect, the Court finally settles upon *Summers* v *Tice*, 33 Cal 2d 80; 199 P2d 1 (1948), as controlling, even though the Court readily notes that it is so factually disparate that *Summers* had to be "tailored" to fit DES. (Opinion, p. 13)

It is clear that *Summers*—recast now in stone by the Restatement of Torts, 2d, §433(B)(3)—does not truly fit the case at bar, as this Court conceded at Opinion, p. 11. Chief Justice Williams writes, "the situation in *Summers* is substantially and significantly distinguishable from this DES litigation, although it is not sufficiently so to make the theory of alternative liability entirely inapplicable." (Opinion, pp. 11-12) Defendant Squibb's belief that the two cases are not even remotely the same draws support from the Opinion. The Court's Opinion, pp. 12-13, recites at length and with great candor the vast and fundamental differences between *Summers* and the DES cases:

> "*Summers* involved one plaintiff and two defendants. This case involves 180 plaintiffs, some of whom were injured directly and some derivatively, and at least 16 defendants. In *Summers*, all the parties who could have caused harm to the single plaintiff were before the court. Here, whether the plaintiffs have brought all defendants before the court is a contested issue. The plaintiffs claim they have sued all know manufacturers of stilbene derivatives who promoted the drugs to the medical profession in Michigan for use in pregnancy during the period between 1947 and

1964. Defendants assert, however, that there are several hundred defendants that should be before the court if our requirement of the presence of all those who could have caused the plaintiff's injury is to be met.

"In *Summers*, the asserted negligence and the injury resulting therefrom, and the activity of all the parties, occurred at essentially the same time and at one place, providing so-called simultaneity. Here, the alleged tortious activity occurred over a span of almost two decades and conceivably through the United States.

"Perhaps the most fundamental, and arguably the most important, factual difference between *Summers* and this case is that in *Summers* each defendant was negligent toward the sole plaintiff; each could have caused the injury to the plaintiff although only one in fact did so. Here, the plaintiffs do not even claim that each of the defendants was negligent toward each of the plaintiffs. Therefore, each of the defendants in this case could not have caused injury to each of the plaintiffs. Stated differently, in *Summers*, each defendant was negligent toward *the* plaintiff; here, each defendant was negligent toward *a* plaintiff, but each defendant was not negligent toward *each* plaintiff. Thus, all defendants were not negligent toward each plaintiff, and each defendant could not have caused each plaintiff's injury." (Emphasis supplied by the Court.)

This Court is not in error in finding that the traditional legal and evidentiary safeguards of requiring an injured party to prove that a firm manufactured a product which was defective and which caused the injury is conceptually derived from a well-founded concern that without such a rule, damages against a manufacturer or distributor could

be assessed greatly out of proportion to the acts proximately causing the injuries. The Court is correct in observing that the products liability causation rule evinces a legitimate rationale that the allocation of moral blame should be a prerequisite to the finding of and award of damages. (Opinion, pp. 7-8, fn. 8) But these laudable observations, while correct, are actually secondary to a loftier freedom—the United States Constitution itself. The due process clause is an integral part of the fundamental, organic law of the land. As Defendant Squibb views it, that law of the land is no more, and no less, than not punishing a criminal or civil defendant until appropriate relevant facts and basic legal elements against him are proven. The sympathy and concern that this Court feels for the innocent Plaintiffs in the instant case is not, standing alone, constitutionally sufficient to cause a taking of the property of Defendants without a prior showing of tort fault of each Defendant so held liable—the essence of "due process". The Court's acceptance of the doctrine of alternative liability is based upon concededly inapposite cases. The alternative liability doctrine allows the result—oriented taking of Defendants' property to be accomplished without any proof of fault and without significant prior thought for what such a judicial feat may do to the concepts of what is organically permitted—or forbidden. This rehearing gives this Court an opportunity to reconsider whether the doctrine should be accepted in light of the United States Constitution.

At least one court considering alternative liability has declined to accept it as an unlawful taking of property. In *Namm* v *Charles E Frosst & Co, Inc,* 178 NJ Super 19, 427 A2d 1121 (1981), the court, in rejecting the theory of alternative liability in that DES case, voiced its concern about the deprivation of constitutional rights that would result from acceptance of an alternative liability theory:

"The application of the principle of alternative liability to any one or all of the 44 defendants herein would impose liability without fault upon anyone who manufactured a product manufactured by others as well. It would result in the taking of the property of all the named defendants in order to pay for harm which may have been caused by only one of the defendants, or even by one who is not a party to the lawsuit, who is unknown to the defendants, over whom they have no control or even any meaningful contact." 427 A2d 1121, 1128.

Judge Moore, in dissent in this case, noted in the Michigan Court of Appeals *Abel* Opinion, 94 Mich App 59, 77, 91, 92; 289 NW2d 20 (1979), as follows:

"Even where there is an otherwise constitutionally sound policy established legislatively, like no-fault insurance, the constitutional validity fails unless there is reasonableness and insurable or actionable protection available to the group. There must be some fault directly proven against the manufacturer, or some activity done or position taken to create liability even through a member of a group.

"To say it another way, absent legislative action and legal responsibility springing, therefrom, one may not be obligated for the fault of a fellow lawyer, or doctor, or engineer, or a drug manufacturer. Both due process and equal protection so protects all of us. The collective liability theory violates due process and equal protection guarantees of the Constitution. The courts cannot create a remedy which is in violation of constitutional law.

"The naked application of the collective liability theory would result in a taking of the property of all of the defendants in order to pay for harm which may have

been caused by the conduct of only one of the defendants or even by one who is not a party to this lawsuit, over whom the defendants have no control or with whom they have no meaningful contact. Due process requires that a state action which deprives a person of his property must have a rational basis, it must not be arbitrary."

The general requirement of the law of products liability—that plaintiffs be compelled to prove that each of the defendants against whom damages are sought is, in fact, factually and legally "guilty" in the civil law—is the *sine qua non* which justifies the transfer of wealth from one person, the defendant, to another, the plaintiff. To deprive a defendant of his property is still (or should be) a drastic act, notwithstanding the present onslaught of ever-new theories of expanding civil liability and the constant erosion of traditional defenses debated daily in the country's legislative chambers and accomplished often in the appellate courtrooms of our nation. No person—even the manufacturer of an allegedly deleterious substance—should ever be stripped of his property without a full and fair hearing or trial which makes relevant the inquiry of proximate causation of injury to another. In the same sense that it would be abhorrent to due process to allow a proven tortfeasor to escape justice by avoiding the paying of reasonable damages to a person he has injured, it is also an incalculable affront to the federal constitution to suggest that an injured person—an object of sympathy to be sure—should nevertheless be empowered to strip property from another as compensation without proof, without the certainty offered by the civil preponderance standard and without any definable inkling that the correct wrongdoer or wrongdoers is or are, in fact, before the Court. Such may be compensation, but it is neither just nor fundamentally right to take it in such a fashion.

There is no pretense or claim that any of the 113 Plaintiffs can clearly identify what substance, if any, was used or ingested, or which manufacturer or distributor, if any, is ultimately responsible for the injuries suffered. A portion of fn. 14 of the Opinion, p. 13, admits that if not every single one of the possible manufacturers or distributors is before the Court, an injustice may result, quoting *Sindell* v *Abbott Laboratories,* 26 Cal 3d 588, 603; 163 Cal Rptr 132; 607 P2d 924 (1980). And yet, some of the Defendants are already indisputably missing from this litigation, having previously been granted summary judgment, as observed by fn. 4 of the Opinion, p. 4. Only about one-half of the original 30 Defendants remain. Despite Plaintiffs' claims about "all" 16 Defendants who sold in Michigan being present before the Court, Plaintiffs know that a 1977 review by a medical researcher using the Physicians' Desk Reference of years past showed that over 300 such manufacturers or distributors existed who created or sold synthetic estrogens from 1947 through 1964.[1] And even if "all" 16 manufacturers who distributed in Michigan are before the Court, are *none* of the 113 Plaintiffs unable to identify the manufacturer ever to be placed residing in another state, or with a non-Michigan prescription source, or with no evidentiary responsibility to determine where Plaintiffs' mothers obtained the subject drugs? A number of the Plaintiffs' mothers clearly obtained the drugs, if at all, in many states other than Michigan. See Appendix 100a, 176a, 186a, 192a, 217a, 223a, 102a, 105a, 107a, 109a, 111a, 113a, 115a, 117a, 119a, 121a, and 123a.

---

[1]Dr. Jerome Maas' Affidavit, dated January 28, 1977. See 278a to 280a. See also, Dr. Maas' Supplemental Affidavit, dated March 21, 1977. See 289a to 292a.

Even if Plaintiffs had named *all* 16 or 200 or 300 potential DES or other synthetic drug manufacturers or distributors before the Court—something Defendant Squibb denies Plaintiffs have done or can do—nevertheless, in many, many cases, Defendant Squibb may be required to pay all or 1/16th or 1/200th or 1/300th or some fractional share of a plaintiff's assessed damages without the slightest hint that it was a Squibb drug that negligently caused the injury.[2] Is that possible—within constitutional due process limitations? We say, with utter confidence, that it is not possible. The Court, in our view, may not regard the Plaintiffs' constitutional rights to a fair trial as superior or as paramount over those of Defendant Squibb's. A societal value judgment made by this Court that it is more socially acceptable to resolve a total uncertainty of fault by depriving Defendant Squibb of its property rather than by compelling the innocent Plaintiffs to sustain their losses (when the innocent Plaintiffs cannot prove the tort by all of the rules previously deemed fair), is a decision which cannot pass constitutional muster. In our view, the due process clause forbids the stripping of Defendant's property from it by mere chance or by guesswork applied to 183 Plaintiffs and 16 or 200 or 300 Defendants. The Restatement of Torts, 2d, §433(B)(3), should not become a judicial lottery. When Plaintiffs state "all" Defendants are before the Court—and Defendants can show several hundred more who are not—the imposition of the alternative liability doctrine is, at best, a compromise with the constitution.

---

[2]Since, under Michigan law, if Defendant Squibb is jointly and severally held liable with 16 or 200 or 300 other manufacturers or distributors, the Plaintiffs can execute solely on the property of Defendant Squibb. See the discussion of this *infra* at p. 31, fn. 7.

The federal constitutional guarantee of due process extends to state action through judicial decisions as well as those taken by the executive or legislative departments of the state. *Brinkerhoff-Farris Trust & Savings Co* v *Hill*, 281 US 673, 680 (1930). In its purest form, "due process of law" implies a conformity with natural and inherent principles of justice which forbid the arbitrary taking of another's property. *Holden* v *Hardy*, 169 US 366 (1898). Certainly, at least, the traditional notions of due process of law are of the essence of fair play, prohibiting government from arbitrary actions and furnishing the matrix of fundamental fairness. *Galvon* v *Press*, 347 US 522 (1954); *Slochower* v *Board of Higher Education of New York City*, 350 US 551 (1956); *Crooker* v *California*, 357 US 433 (1958). Any involuntary transfer of property must, in order to be sustained, afford the party prejudiced due process of law, the *sine qua non* for such legal authority. The essence of such due process is for the defendant to be given a fair chance to rebut the criminal or civil charges made and to resist the punishment sought. The concept of substantive due process is to require a fair trial before an impartial tribunal and *then*, if an adverse judgment be entered, deprive defendants of property rights. The Michigan Courts so considering the federal due process clause have agreed. *Rockwell* v *Crestwood School District Board of Education*, 393 Mich 616, 633; 227 NW2d 736, 743 (1975); *Rehabilitation Center, Inc.* v *Blue Cross/Blue Shield of Michigan*, 93 Mich App 357; 287 NW2d 236 (1979) (recognizing the constitutional rule).

In *Vachon* v *State of New Hampshire*, 414 US 478 (1974), the Supreme Court of the United States overturned a conviction based upon a record which did not present relevant evidence of a necessary element of an offense. It was held that such state action deprived de-

fendant of due process of law. In the instant civil case, the action of the Michigan Supreme Court is virtually identical since this Court has swept away all of the traditional elements of the civil tort of negligence in products liability, including the fundamentally fair concept that each plaintiff must show exposure to a Squibb drug before liability against Defendant Squibb can be triggered. If, as in *Vachon*, it is a violation of substantive due process to affirm a criminal conviction without a necessary element of the crime being proven, why would it ever be constitutionally permissible to sustain a tort verdict against a civil litigant in those cases as to whom the Plaintiffs, the Courts, and the Defendants themselves are in complete doubt as to whether a particular party is involved or not?

Playing the statistical averages—that Defendant Squibb will sometimes pay to Plaintiffs tort judgments that are (on a sheer guesswork basis)—fair or totally unfair (after all, there is no absolute certainty on the part of Plaintiffs and so it is uneven to expect more from Defendants)—is a patchwork system designed to work with only a blind eye to proof of actual fault. Since the Plaintiffs cannot give the Courts any evidence, under the alternative liability doctrine—"DES-unique"—presumably, the Defendants in many such cases will be equally uncertain. Therefore, Plaintiffs will prevail and the Defendants will lose the cases without Plaintiffs being required to prove to the satisfaction of the jury to a civil preponderance that *any* tort defendant in the courtroom is the right one. The "fundamentally fair" concept that the plaintiff show tort fault on the part of a defendant—or defendants—is rooted in the substantive due process clause. To abolish it by the "DES-unique" vehicle of alternative liability is to exempt alleged DES Defendants

from substantive due process considerations—the most fundamental being that such Defendants have *some* causal relationship to a Plaintiff's injuries. If it is a matter of no concern to the Michigan Supreme Court that numerous Defendants will be called upon to transfer their property to claimants in cases where *nobody* knows or can prove any causal connection or relationship to a product, then the law of products liability has become an exercise in raw power, suspending the due process clause in favor of the Restatement of Torts, 2d, and beating the unwilling *Summers* precedent into "DES-unique" submission.

If this be so, the authority of the Supreme Court of the United States is contrary. Repeatedly, that court of last resort has reversed state court judgments which have attempted to relieve one litigant (usually a prosecutor in a criminal case) from inconvenient burdens of proof that tie the actions of a defendant to his civil or criminal punishment. See, for example, *Thompson* v *City of Louisville*, 362 US 199, 206 (1960 (". . . it [is] a violation of due process to conflict and punish a man without evidence of his guilt.") See, also, *DeJonge* v *State of Oregon*, 299 US 353, 362 (1937); *Cole* v *State of Arkansas*, 333 US 196, 201 (1948); *Harris* v *United States*, 404 US 1232, 1233 (1971) (Opinion of Douglas, J); *Johnson* v *State of Florida*, 391 US 596 (1968); *Adderley* v *State of Florida*, 385 US 39, 44 (1966).

Without fear of contradiction, Defendant Squibb suggests that, indeed, the Opinion in the instant case affords Plaintiffs a way to "circumvent" the traditional products liability legal and evidentiary safeguards. (Opinion, p. 2) Indeed, Plaintiffs can now "bypass" the otherwise insurmountable identification question. (Opinion, p. 2) But these fundamental legal and evidentiary points are the essence of Defendant's protection from unconstitutionally

being required to pay tort damages as to which, by all admissions, no one has the slightest idea if Defendant Squibb is being called upon as the right Defendant to pay the right Plaintiff.

It is, of course, more facile to honor the unprovable claims of the innocent Plaintiffs in this case than it is to respect the constitutional rights to due-process-level certainty as to Defendant Squibb. But the staunch defense of constitutional principles has always been a task designed not for the faint of heart but for the courageous who willingly take up the unpopular cause. It is presently hoped that this Court will grant a Rehearing of its February 6, 1984 Opinion in order to afford a debate about the constitutional propriety of what the Court has done. To do otherwise is to enshrine the intellectual minutiae of §343(B)(3) of the Restatement of Torts, 2d, over fundamental constitutional principles and to displace the bedrock ideals articulated by substantive due process as embraced by the Fifth and Fourteenth Amendments to the Constitution of the United States in favor of a 1948 California appellate decision which is admitted to be profoundly distinguishable.

ARGUMENT II

THIS COURT'S OPINION CREATES A MANDATORY PRESUMPTION AND A LATERAL TRANSFER OF THE BURDEN OF PROOF WHICH VIOLATES DEFENDANT'S RIGHTS TO PROCEDURAL DUE PROCESS.

Since it is patent that Plaintiffs are simply unable to identify the manufacturer or distributor of the estrogen product to which they were allegedly exposed (Opinion, p. 2), liability against Defendant Squibb attaches if Defendant Squibb cannot exonerate itself by showing that it did not cause each Plaintiff's injury. (Opinion, p. 16) Put

one way, the burden of proof of the elements of the tort normally attendant in products liability cases is eliminated for Plaintiffs, but, rather, is laterally transferred to each of the Defendants. (Opinion, pp. 14, 16) Put concisely, if each of the Plaintiffs shows (1) that all Defendants/tortfeasors are before the Court who manufactured DES, DSD, or dienestrol; (2) which products their mothers ingested; (3) which products were distributed in Michigan; and (4) that such products caused the type of injuries of which the Plaintiffs complain, *then* there is a mandatory presumption of injury causation and tort liability shifted to each of the Defendants to disprove. (Opinion, pp. 14-16) Furthermore, as indicated above, the essential underpinning of such "DES-unique" alternative liability is the mandatory factual presumption that all Defendants/tortfeasors are before the Court and, therefore, one unidentified member of Defendants caused Plaintiff's injury.

Such mandatory presumptions—that (1) the tortfeasor who caused Plaintiff's injury is actually before the Court; and (2) therefore, the Court is justified in shifting tort liability *in toto* over to the Defendants to disprove *inter se*—are only to be upheld as valid under basic concepts of fundamental procedural due process if there is a rational connection between the facts established and the facts to be presumed. See *Van Slooten* v *Larsen*, 410 Mich 21; 299 NW2d 704 (1980), *appeal dismissed* 455 US 901 (1981); *Leary* v *United States*, 395 US 6, 36 (1969); *People* v *Gallagher*, 404 Mich 429, 438; 273 NW2d 440, 443 (1979). If there is no such rational connection, due process of law is violated. *Van Slooten*, at 51. See, also, *Turner* v *Department of Employment Security and Board of Review of the Industrial Commission of Utah*, 423 US 44 (1975); *Stanley* v *Illinois*, 405 US 645 (1972); *Cleveland Board of Education* v *LaFleur*, 414 US 632 (1974); *United States Department of Agriculture* v *Murry*, 413 US 508 (1973);

Bell v *Burson*, 402 US 535 (1971); *Heiner* v *Donnon*, 285 US 312 (1932).

As such, to have any rational validity at all, the Court can espouse "DES-unique" alternative liability only if the Court has a belief—not clearly erroneous—that *all* tortfeasors are before the Court. If Defendant Squibb can show that all tortfeasors are *not* before the Court, then the mandatory presumptions established by the Opinion are not rational and violate Defendant Squibb's procedural due process rights.

Defendant Squibb can certainly make that showing. Since the Opinion itself (Opinion, p. 4, fn. 4) notes that Plaintiffs originally sued 30 synthetic estrogen manufacturers or distributors and that several have now escaped by summary judgment, a conclusion can be reached that, of the 16 companies still remaining, Plaintiffs have only half of the 30 Defendants originally alleged by Plaintiffs to be Michigan manufacturers or distributors. The Court should be greatly troubled that it is putting into place a legal doctrine which—from the plain legal history set forth in the Court's own Footnote 4—has no rational basis upon which to rest. Alternative liability—"DES-unique" —adopted by this Opinion is doomed *ab initio* because—with 14 Defendants already missing—there is now a distinct possibility that the real, but unidentified, tortfeasor is not before the Court in those cases in which the alternative liability doctrine is invoked. If, as Defendants contend the number of manufacturers or distributors of synthetic estrogen is much greater,[3] the chances become

---

[3]Defendants' Appendix contains the Affidavits of Jerome M. Maas, M.D., found at 278a-280a and 289a-295a, which found in America over 300 such manufacturers and distributors of synthetic estrogens from 1950 to 1964.

proportionately greater that the Court is using a mandatory presumption which is false and irrational. In any event, whether Plaintiffs are correct—or Defendants are—the mandatory presumption is palpably incorrect. See this Court's Opinion, Footnote 4.

The mandatory presumption is further shown to be irrational because for certain of the Plaintiffs, the drugs were purchased in many other states outside of Michigan. See Appendix 100a, 176a, 186a, 192a, 217a, 223a, 102a, 105a, 107a, 109a, 111a, 113a, 115a, 117a, 119a, 121a, and 123a. Plaintiffs' claims in such cases that they have *all* the manufacturers or distributors of the drugs *in Michigan* and, therefore, "DES-unique" alternative liability is proper is, in fact, demonstrably incorrect since these Plaintiffs did not purchase the drug in Michigan *ever* in the first place. The mandatory presumption that all tortfeasors are present is not rationally connected to the facts shown. The irrational application of the doctrine of alternative liability would be unconstitutional as violative of due process in these cases. "The power to create presumptions is not a means of escape from constitutional restrictions." *Bailey* v *State of Alabama*, 219 US 219, 239 (1910).

For example, this Court has previously held that a conclusive, gender-based presumption of dependency in workers' compensation proceedings deprived a plaintiff of constitutional rights. See *Day* v *W A Foote Memorial Hospital, Inc*, 412 Mich 698; 316 NW2d 712 (1982).

Even if the mandatory presumption were otherwise arguably rationally connected, procedural due process forbids the taking of Defendant's property if the presumption prerequisite thereto is the basis of a mandatory or permanent (or irrebuttable) presumption which is "not necessarily or universally true in fact". See *Vlandis* v *Kline*, 412 US 441, 452 (1973); *Van Slooten* v

Larsen, 410 Mich 21, 50; 299 NW2d 704, 710 (1980), *appeal dismissed* 455 US 901 (1981). Taking the contentions of the 113 Plaintiffs, who claim that they cannot identify any of the Defendants to be the causally related manufacturer or distributor at face value, if the burden of proof is then shifted to the Defendants, it is no answer that in some of the cases, Defendants may be able to allocate or identify responsibility, because, in some other cases, the total uncertainty of the Plaintiffs is merely laterally transferred over to the Defendants who, in such cases, will be burdened with the liability for damages since, in such cases, they, too, will be unable to disprove their guilt. Insofar as these latter cases are concerned, when the Defendants are unable to exonerate themselves after the shift of burden of proof takes place, the total lack of certainty gives the Plaintiffs an unconstitutionally unfair advantage because the Defendants in such cases are saddled with a *de facto,* permanent, *de facto,* irrebuttable, and *de facto,* conclusive mandatory presumption which, for these cases, will never be defeated. As indicia of the unfairness of the alternative liability doctrine, this Court has candidly found that it matters not at all that in some of the DES cases the Defendants are to be held liable despite lack of access of sources of proof. The Court's opinion, at p. 15 states:

> "We note in passing that defendants' access to evidence of causation is not a relevant factor. The California court in *Summers* did mention that '[o]rdinarily defendants are in a far better position to offer evidence to determine which one caused the injury.' 33 Cal 2d 866 . . . . Even as a factor within that doctrine, the defendants' access to evidence as a controlling consideration has been criticized."[4]

---

[4]Although the Plaintiffs' alleged lack of access to evidence *is* controlling. See Opinion, pp. 10, 11, 14 and 15.

At the point that this Court determines—as it apparently has—that the ability of Defendant Squibb to defend itself is no longer relevant, and that Defendant's access to evidence is no longer a controlling consideration[5]—then Defendant Squibb must reply by relying upon the procedural guarantees of the due process clause of the Constitution of the United States. In *Heiner* v *Donnon*, 285 US 312, 329 (1932), the court held:

> "The Court has held more than once that a statute creating a presumption which operates to deny a fair opportunity to rebut it [the presumption] violates the due process clause of the Fourteenth Amendment."

In those cases where *both* the plaintiffs and defendants cannot prove the identity of the manufacturer and/or distributor, under this opinion, Defendant Squibb will fail and be subjected to joint and several liability. Procedural due process requires that there be an opportunity to present every available defense. *Lindsey* v *Normet*, 405 US 56, 67 (1972); *American Surety Co* v *Baldwin*, 287 US 156, 158 (1932). See, also, *Nickey* v *State of Mississippi*, 292 US 393, 396 (1934). A tort verdict bathed in such complete uncertainty is not consonant with procedural due process.

This lack of certitude and shifting of the burden of proof has been presented before. In *Western & Atlantic Railroad* v *Henderson*, 279 US 639 (1929), an analogous situation warranted the striking down of a very similar

---

[5]This means that in Michigan, a single DES plaintiff in such a case can execute on the property of Defendant Squibb alone, without anyone having the faintest idea if it is Defendant Squibb which, in fact, is the responsible manufacturer.

presumption which was—as here—"rebuttable" on the surface, but, in application, was such a large hurdle to a fair trial that the Supreme Court felt justified in nullifying the presumption on constitutional grounds. The statute before the Court permitted a jury to award damages against defendants in cases where train collisions had taken place unless the railroad could prove that it had exercised "all ordinary and reasonable care and diligence, the presumption in all cases being against the company". *Henderson,* at 640. Plaintiff charged wrongful death due to negligence in six areas, but, finally, Plaintiff provided no evidence on other claims. The Court reversed a judgment in favor of plaintiff Henderson, holding that there was no rational basis upon which to shift the burden of proof on each separate issue of negligence. In order to satisfy due process, there must be "a rational connection between what is proved and what is to be inferred". 279 US at 642. The Court held that a "legislative fiat may not take the place of fact in the judicial determination of issues involving life, liberty or property". *Henderson,* at 642. This is so because ". . . a presumption that is arbitrary, or that operates to deny a fair opportunity to repel it, violates the due process clause of the Fourteenth Amendment". *Henderson,* at 642.[6]

While it is certainly true that a presumption may not be a deprivation of due process if there is a meaningful and adequate opportunity to rebut or disprove the facts so presumed, *Weinberger* v *Salfi,* 422 US 749, 772 (1975), the courts considering the constitutional question have

---

[6]Nor is it significant that the Court here creates the presumption, because, as *Henderson* notes at Footnote 1, the state courts repeatedly construed the statute by judicial decision. *Henderson,* at 642.

had great difficulty when the presumption is permanent and irrebuttable, either by operation of law or *de facto*. *Vlandis* v *Kline*, 412 US 441, 446 (1973); *Cleveland Board of Education* v *LaFleur*, 414 US 632 (1974); *Stanley* v *Illinois*, 405 US 645 (1972); *United States Department of Agriculture* v *Murry*, 413 US 508 (1973); *Bell* v *Burson*, 402 US 535 (1971); *Carrington* v *Rash*, 380 US 89 (1965). The due process clause requires a more individualized determination; one that is not formed on rules which are "neither necessarily nor universally true". *LaFleur*, at 645, 646. In Defendant Squibb's view, in those cases where both plaintiffs and defendants cannot identify the specific manufacturer or distributor in question, Defendant Squibb stands at risk and liable to the Plaintiff's entire post-judgment execution, leaving up to Defendant Squibb—whom no one knows is actually the "guilty" party—contribution (if it exists) or loss (if it does not or if co-defendants are not judgment-proof). Since in these cases, *both* parties will not know the truth, Defendant Squibb is denied procedural due process because there is no fair opportunity to rebut the mandatory presumption. *Heiner* v *Donnon*, 285 US 312, 329 (1932).[7]

---

[7]Similarly, Defendant Squibb may be singled out by a plaintiff to judgment—bearing not just the damages. This shifts not just the burden of proof, but *all* damages in violation of substantive due process. The Opinion, pp. 4, 18, 16, concedes that Plaintiffs seek joint and several liability. Under applicable Michigan law, the imposition of joint and several liability means that a plaintiff may choose *any* of the defendants so liable under the alternative liability doctrine—"DES-unique"—against whom to enforce the entire judgment. *Bowerman* v *Detroit Free Press*,

(Continued on following page)

To shift the burden of proof on causation to each of the Defendants is, in effect, to create a mandatory presumption of causation. A mandatory presumption is a "troublesome evidentiary device". *County Court of Ulster County* v *Allen*, 442 US 140, 157 (1979). Such a presumption ". . . tells the trier that he or they *must* find the elemental fact upon proof of the basic fact, unless the defendant has come forward with some evidence to rebut the presumed connection between the two facts". *Allen*, at 157. The Opinion thus creates a mandatory presumption of causation (and therefore liability) by, in effect, requiring Plaintiffs to prove only the four elements listed on pp. 14-15.

Due process requires a proper standard of proof and an appropriate placement of the burden of proof. In *Matthews* v *Eldridge*, 424 US 319 (1976), the court identified three factors, a consideration of which assists in the determination of whether a particular standard of proof satisfies due process. Those three factors are as follows: first, the private interests affected by the proceeding; secondly, the risk of error created by the state's chosen procedure; and thirdly, the countervailing governmental interest supporting the use of the challenged procedure. The overall consideration of these factors was summarized by

---

Footnote continued—

279 Mich 480, 489-490; 272 NW 876, 880 (1937); *Bishop* v *Plumb*, 363 Mich 87, 90; 108 NW2d 813, 814 (1961). Since there will be many cases where not a single litigant will have any idea whether a single defendant paying the entire judgment is, in fact, the ultimately responsible party, the inherent, fundamental unfairness of this approach translates to a deprivation of *both* procedural and substantive due process.

the court in *Addington* v *Texas*, 441 US 418, 423 (1979), when it articulated the interplay between a party's due process rights in light of the burden of proof imposed upon that party:

> "The function of a standard of proof, as that concept is embodied in the due process clause and in the realm of factfinding, is to 'instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.' [Citation omitted.] The standard serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.
>
> "Generally speaking, the evolution of this area of the law has produced across a continuum three standards or levels of proof for different types of cases. At the one end of the spectrum is the typical civil case involving the monetary dispute between parties. Since society has a minimal concern with the outcome of such private suits, plaintiff's burden of proof is a mere preponderance of the evidence. The litigants thus share the risk of error in roughly equal fashion."

The *Addington* court's instruction that the function of the burden of proof is to minimize the risk of erroneous decisions and to allocate the risk of error equally between the litigants highlights the impropriety of this Court's determination that, notwithstanding the fact that the instant Plaintiffs do not have access to the sources of proof, the Defendants, who suffer from the same impediment, nevertheless are in a better position to assume the burden of proof. In other words, this Court's placement of the burden of proof on Defendants falls short of meeting the demands of due process, because it imposes a burden upon

Defendants that cannot be met, and thereby erects an unreasonable barrier to the goal of an equal sharing of the risk of error.

The *Addington* decision was of particular concern to the court in its later Opinion in *Santosky* v *Kramer,* 455 US 745 (1982). That court, in paying heed to the *Addington* decision, emphasized the importance of due process principles in the articulation and placement of the burden of proof in a given case:

> "*Addington* teaches that, in any given proceeding, the minimum standard of proof tolerated by the due process requirement reflects not only the weight of the private and public interests affected, but also a societal judgment about how the risk of error should be distributed between the litigants.
>
> "Thus, while private parties may be interested intensely in a civil dispute over money damages, application of a 'preponderance of the evidence' standard indicates both society's 'minimal concern with the outcome,' and a conclusion that the litigants should 'share the risk of error in roughly equal fashion.' " 455 US 745, 755.

As explained by the *Santosky* court, the standard of proof in a criminal action is designed to exclude as nearly as possible the likelihood of an erroneous judgment. Consequently, the stringency of a "beyond a reasonable doubt" standard bespeaks the weight and gravity of the private interest affected, society's interest in avoiding erroneous convictions, and a judgment that those interests together require that society impose almost the entire risk of error on itself. To the contrary, the nature of a civil case requires, as between those most interested in its outcome, those being the parties to the action, that the risk of error be equally distributed.

Accepting that the three *Eldridge* factors compelled different and distinct standards of proof in criminal and civil actions, the *Santosky* court cautioned against development of different standards of proof framed to meet particular intricacies of each case:

> "But this Court has never approved case-by-case determination of the proper *standard of proof* for a given proceeding. Standards of proof, like other 'procedural due process rules[,] are shaped by the risk of error inherent in the truth-finding process as applied to the *generality of cases*, not the rare exceptions.' *Matthews* v *Eldridge*, 424 U.S., at 344, 96 S. Ct., at 907." (Emphasis supplied.) Since the litigants and the factfinder must know at the outset of a given proceeding how the risk of error will be allocated, the standard of proof necessarily must be calibrated in advanced. Retrospective case-by-case review cannot preserve fundamental fairness when a class of proceedings is governed by a constitutionally defective evidentiary standard." 455 US 745, 757.

This Court's decision contravenes the due process notion that standards of proof are to be developed by a consideration of the general nature of cases and not on a case-by-case basis. By acceptance of the unique and peculiar standard of proof for DES-type cases, this Court has upset the equally balanced "risk of error" factor by placing upon Defendants an unjustified burden of accepting all chance of error. As this Court has conceded, and as has been understood in numerous other DES-type cases throughout this country, there exists in each case the very real possibilities that the true wrongdoer has not been named a party to the suit and/or that the named Defendants will have to pay damages for injuries not caused by their products.

To conclude, Defendant Squibb respectfully suggests that sufficient grounds exist to warrant the granting of a rehearing. It has been shown that the presumptions created herein are not rationally connected between the facts established and the facts to be presumed. It has been shown that the shifting of the burden of proof to the Defendants is the lateral transfer of the unknown from one party to the other, and is not constitutionally justified since, in such cases, defendants are no more able to defend themselves than plaintiffs are to prosecute their civil claims. Negating the plaintiff's burden of proof —or shifting it—is often found to be procedurally defective under due process concepts.

Rehearing is appropriate to allow argument on this matter.

ARGUMENT III

THE COURT'S OPINION DEPRIVES DEFENDANT SQUIBB OF EQUAL PROTECTION OF THE LAW.

In the past, the Michigan courts have had no difficulty recognizing that arbitrary or unfair classifications which worked invidiously discriminatory or irrational distinctions against injured parties bringing suits for personal injuries may, and have, placed unconstitutional barriers in the path of such litigants as contrary to the equal protection of laws clause of the Fourteenth Amendment of the United States Constitution. See, for example, *Reich* v *State Highway Department*, 386 Mich 617; 194 NW2d 700 (1972) (unusually short notice provision protecting governmental but not private tortfeasors stricken down); *Gallegos* v *Glaser Crandell Co*, 388 Mich 654; 202 NW2d 786 (1972) (exclusion of agricultural workers from

workers' compensation is irrational and individually discriminatory); *Fox* v *Employment Security Commission*, 379 Mich 579; 153 NW2d 644 (1967) (recipient of weekly workers' compensation benefits suffered reduction of unemployment compensation where lump-sum workers' compensation award not reduced *held* irrational); *Day* v *W A Foote Memorial Hospital, Inc*, 412 Mich 698; 316 NW2d 712 (1982) (conclusive gender-based presumption of dependency in workers' compensation); *Bowser* v *Jacobs*, 36 Mich App 320; 194 NW2d 110 (1971) (personal injury classification stricken down as having been made without the force of compelling logic).

The instant Opinion ordains that the phylum of tort defendants generally—or even products liability defendants specifically—shall now have a genus known as "DES-unique" defendants who are not entitled to the myriad substantive, procedural, and legal protections otherwise afforded to those tort defendants fortuitously placed outside of the "DES-unique" classification by the Court.

There is no doubt but that the Court intends to discriminate against a manufacturer or distributor of synthetic estrogens by carrying out a hitherto unknown cause of action which is ". . . modified, however, to accommodate the unique facts of this unusual litigation". (Opinion, p. 12) To do so, the Court is willing to take a concededly inapposite precedent, *Summers* v *Tice*, 33 Cal 2d 80, 199 P2d 1 (1948), which is noted to be "distinctly different", but which the Court will tailor ". . . to accommodate the unique facts of this case . . . ." (Opinion, p. 13) The cause of action so authorized is both "DES-unique" and "DES-modified". (Opinion, pp. 13-14) The "brand name" classification is so sharply drawn in this case that this Court had to carve it out with its own "DES-unique" sobriquet.

What is the hallmark of this *sui generis* legal doctrine? Under this Court's Opinion, Plaintiffs need not show that each of the Defendants sought to be held liable have not caused the Plaintiffs' injuries, or, indeed, even that they have used or been exposed to the products in question; thereafter, Defendants must prove lack of causation or otherwise be subjected to joint and several liability. (Opinion, pp. 14-16)

What rights do other products liability tortfeasors similarly situated have which, by this Court's Opinion, are to be denied to Defendant Squibb? First of all, the requirement that a products liability plaintiff prove and identify manufacturer, defect, causation, and damages is eliminated. This fundamental point of law is established in the common law. See *Piercefield* v *Remington Arms Co, Inc*, 375 Mich 85, 98-99; 133 NW2d 129, 134-135 (1965); *Heckel* v *American Coupling Corp*, 384 Mich 19; 179 NW2d 381 (1970) ("as defendant says in his brief, all of these cases stand for the proposition that there must be a defect attributable to the manufacturer and a causal relationship between that defect and the injury complained of in order for there to be recovery . . . .") The burden of Plaintiffs' proof is additionally codified in otherwise applicable jury instructions. See SJI2d 25.32. See, also, SJI2d 25.01, 25.02, 25.03, 25.04, 25.12, 25.22. Under SJI2d 25.32, Plaintiffs in the instant cases would otherwise be required to prove on an individual basis (1) that Defendant Squibb manufactured the product which created an unreasonable risk of harm; (2) that this harm was foreseeable *at the time the product was manufactured;* (3) that Defendant Squibb failed to exercise reasonable care in manufacturing the product so as to eliminate the risk of harm; (4) that the Plaintiff was injured as a result of Defendant Squibb's alleged negligence, which has to be found to have been a proximate cause.

The burden of proof is also statutorily granted to Defendant Squibb under MCLA 600.2945; MSA 27A.2945, since this statute extends to *any* legal or equitable theory brought for personal injuries *caused by or resulting from* the manufacture of a product. MCLA 600.2945; MSA 27A.2945.[8] Furthermore, there are evidentiary industry standards that are in effect for manufacturers which relate to "the time the product was sold or delivered by the defendant to the initial purchaser or user". MCLA 600.2946(1) and (2); MSA 27A.2946(1) and (2).

Furthermore, all other products liability defendants are entitled to the benefit of a statute, MCLA 600.5805 (9); MSA 27A.5805(9), which states, in pertinent part, as follows:

> "[I]n the case of a product which has been in use for not less than 10 years, the plaintiff, in proving a prima facie case, shall be required to do so without benefit of any presumption."

Passed as a part of Products Liability Reform legislation along with MCLA 600.2945; MSA 27A.2945, MCLA 600.5805(9); MSA 27A.5805(9) clearly applies to DES cases to eliminate virtually any evidentiary presumption and, like *In Re Certified Questions, Karl* v *Bryant Air Conditioning Co,* 416 Mich 558; 331 NW2d 456 (1982), the statute is to be retroactively applied to all cases, including, specifically, DES cases. *Keil* v *Eli Lilly & Co,* 490 F Supp 479 (ED Mich 1980). Since alternative liability as a doctrine is essentially a mandatory presumption which

---

[8]The statute is, of course, remedial and is retroactively applied to any and all pending products liability cases. See *In Re Certified Questions, Karl* v *Bryant Air Conditioning Co,* 416 Mich 558; 331 NW2d 456 (1982).

shifts the burden of proof, unlike all other products liability defendants substantially similarly situated, the DES defendants do not obtain the benefit of this statute.

Moreover, the impact of the instant Opinion may greatly prejudice the rights of the Defendants among themselves pertinent to indemnity and contribution rights. Without passing on the merits of such arguments, Defendant Squibb protests that it will be treated differently than all other tort defendants similarly situated.

Consider first the law of common law indemnity in Michigan. At Michigan law, the mere allegation of active tort fault is sufficient to destroy such rights. See *Minster Machine Co* v *Diamond Stamping Co*, 72 Mich App 58; 248 NW2d 676 (1976); *Diekevers* v *SCM Corp*, 73 Mich App 78; 250 NW2d 548 (1976); *Duhome* v *Kaiser Engineering of Michigan, Inc*, 102 Mich App 68; 300 NW2d 737 (1980); *Swindlehurst* v *Resistance Welder Corp*, 110 Mich App 693; 313 NW2d 191 (1981); *Ingram* v *Interstate Motor Freight Systems, Inc*, 115 Mich App 559; 321 NW2d 731 (1982). Presumably, some indemnity defendants may argue that mere imposition of alternative liability is sufficiently active tort fault to defeat common law indemnity. Just as importantly, since each one of the Defendants who are held liable to each of the Plaintiffs under alternative liability will have no idea whether it—or another Defendant—is actually the Defendant who is responsible, the ultimate conclusion may be argued to be that such indemnity does not exist in such cases.

Equally importantly, Michigan law for all tort defendants in the same or similar circumstances holds for a complete allocation of tort fault among the defendants (but not as to plaintiff), contribution liability existing for such tortfeasors distributed in accord with their rela-

tive degrees of fault. MCLA 600.2925b(a); MSA 27A.2925 (2)(a) states:

> "In determining the pro rata shares of tortfeasors in the entire liability as between themselves only and without affecting the rights of the injured party to a joint and several judgment . . . (a) Their relative degrees of tort fault shall be considered."

If there are 16 or 200 or 300 Defendants found liable under alternative liability, upon later contribution, each Defendant will bear exactly 1/16th or 1/200th or 1/300th of liability. Such a ruling deprives each Defendant of his right, for contribution purposes, of being judged comparatively "guilty" or "innocent" along the lines of his own tort fault—or lack of it.

To Defendant Squibb, there is no rational purpose to the classifications and distinctions made against the DES Defendants. The ruling of this Court constitutes an invidious discrimination, an arbitrary stab at justice which strips Defendant Squibb of numerous substantive, procedural, and legal safeguards in a punitory manner. This Court suggests, at p. 10, that the purpose of tort law ". . . is to compensate injured persons . . . ." If so, the alternative liability doctrine is rationally related to the object or purpose stated, but such a holding itself shows the basic inequality of the Court's ruling. The purpose of the law of tort is *not* to provide plaintiffs with compensation, but to give a forum of equally fair consideration to claims *and* defenses. Equal protection of law, as a constitutional guarantee, demands that *all* tort plaintiffs and *all* tort defendants be given the same equal chance to prove *or* disprove claims, not to assure that one side always emerges victorious. Since rationality is the probable test, *Dandridge* v *Williams*, 397 US 471,

487 (1969), *Ortwein* v *Schwab*, 410 US 656 (1973); *United States* v *Kras*, 409 US 434 (1973); *Williams* v *Oklahoma City*, 395 US 458 (1969); *Lindsey* v *Normet*, 405 US 56 (1972), the inquiry is whether the alternative liability doctrine is rationally related to securing a fair trial for all tort litigants. Once tested, it is obvious that the imposition of alternative liability upon Defendant Squibb is merely the transfer of property on the basis of social conscience (in its best light) or an attempt to punish it for allegedly manufacturing a synthetic estrogen (in its worst).

In *Lindsey* v *Normet*, 405 US 56 (1972), applying the rationality test, at 74, the Supreme Court of the United States upheld an extremely short, unique, expedited trial docket for Oregon landlord tenant cases, but only on the basis that both sides had equal access to and knowledge of the facts. *Lindsey*, at 65. Here, the level of uncertainty may be equal, but the punitory attitude of the Court determines that the DES Defendant should pay—unlike any other similarly situated products liability defendant. In *Lindsey*, on an equal protection basis, the Supreme Court of the United States struck down a "double" appeal bond required for tenants-defendants, both indigent and wealthy, who were penalized for taking such appeals, unlike the appellate treatment of any other defendant, indigent or wealthy.

Repeatedly, the Supreme Court of the United States has overruled arbitrary, invidiously discriminatory distinctions between criminal and civil litigants whenever the state has been unable to show a rational purpose to sustain the disparate treatment. *Lindsey* v *Normet*, 405 US 56 (1972); *Ortwein* v *Schwab*, 410 US 656 (1973); *Williams* v *Oklahoma City*, 395 US 458 (1969); *Griffin* v

State of Illinois, 351 US 12 (1956); *Douglas* v *State of California*, 372 US 353 (1963); *Draper* v *State of Washington*, 372 US 487 (1963); *Eskridge* v *State of Washington*, 357 US 214 (1958); *Rinaldi* v *Yaeger*, 384 US 305, 310-311 (1966).

Nor is it any answer to any of this to say that because this is the construction of state products liability law, the action of the court is inviolate. Since court rulings do furnish the basis of "state action", Defendant Squibb is entitled to equal protection of law even if the deprivation thereof is a ruling of the Court. See *New York Times Co* v *Sullivan*, 376 US 254 (1964) (imposition and upholding of civil judgment by Alabama courts); *Eskridge* v *State of Washington*, 357 US 214 (1958) (equal protection violation in free transcript being provided but only if trial judge finds justice will be promoted); *Draper* v *State of Washington*, 372 US 487 (1963) (equal protection violated if trial judge holds that no free transcript for indigent necessary if appeal found patently frivolous).

By abandoning the substantive, procedural, and legal safeguards available to other products liability defendants, but not to Defendant Squibb, the Court has arbitrarily, harshly, and punitorily carved out an irrationally, invidiously discriminatory rule for DES manufacturers and distributors. By emphasizing repeatedly that the doctrine has been "tailored" in a "DES-unique" way, the Court has crossed the line into an unconstitutional classification. The advancing law of tort is required to stop at the border of the equal protection clause. Defendant Squibb respectfully submits that a rehearing should be granted to address this issue, which was previously raised in Defendant's brief at pp. 48-49, but which the Court elected not to discuss. To continue to decline to hear the argument perpetuates the inequality.

K. Trial court affidavits of Jerome Maas, M.D., filed in the Circuit Court for the County of Wayne

Affidavit of Jerome M. Maas, M.D.

No. 74 030 070 NP

AFFIDAVIT

JEROME M. MAAS, M.D., being duly sworn, deposes and says:

1. I reside in Indianapolis, Indiana, and am a physician duly licensed to practice medicine in the States of Indiana and Wisconsin.

2. I am a former employee of Eli Lilly and Company ("Lilly") having retired in April, 1975, and am presently a consultant to Lilly.

3. I am a member of the following professional organizations:

(a) American College of Obstetricians and Gynecologists (Fellow);

(b) U. S. International Foundation for Studies in Reproduction, Inc.;

(c) New York Academy of Science;

(d) Southern Obstetrics and Gynecologic Seminar, Inc.;

(e) American Society for the Study of Sterility;

(f) International Federation of Gynecology and Obstetrics;

(g) International Fertility Association;

(h) Pacific Coast Fertility Society.

4. I am familiar with the facts in this action and make this Affidavit in support of Defendants' Joint Motion for Partial Summary Judgment and pursuant to GCR 1963, Rules 117.2 and 117.3. I have personal knowledge

of the facts recited herein and, if sworn as a witness in this case, would be competent to testify thereto.

5. On the basis of my professional experience, I am familiar with the many synthetic estrogens used for treating complications of pregnancy (i.e., threatened or habitual abortion, premature labor and pregnancy complicated by diabetes) between the years 1947 and 1964.

6. The eighteen drug manufacturers presently defendants in this action produced one or more of the following four types of synthetic estrogens; diethylstilbestrol, diethylstilbestrol diproprionate, dienestrol and hexestrol.

7. Six employees of Eli Lilly and Company, Betty DeHart, William Engle, Lila James, David May, Magdalene Pride and William Reece, reviewed the *American Druggist Blue Books*, the *Drug Topics Red Books*, and *The Modern Drug Encyclopedia and Therapeutic Indexes* for the years 1950 through 1964, to identify companies who offered synthetic estrogens for sale to pharmacists during these years. The *Blue Book* and the *Red Book* are standard references intended primarily for use by pharmacists in ordering drug products. The products are listed in alphabetical order and information on prices of the drugs and their manufacturers is included. The *American Druggist Blue Book* is published by the Hearst Corporation, New York, New York, 10019. The *Red Book* is published by Medical Economics Co., Oradel, New Jersey, 07649. Prior to 1970, it was published by Topics Publishing Co., Inc., New York, New York. The *Modern Drug Encyclopedia* contains detailed information on thousands of drugs and also lists some of their manufacturers. It is currently published by The Yorke Medical Group of the Dun-Donnelly Publishing Corporation, New York, New York.

I have personally reviewed the references listed above for several of the years involved and am familiar with the information contained therein.

8. During the years from 1950 through 1964 over 300 manufacturers of the four synthetic estrogens which could have been used in complications of pregnancy are listed in these standard references as offering such drugs for sale to pharmacists.

/s/ Jerome M. Maas, M.D.
Jerome M. Maas, M.D.

STATE OF INDIANA)
) SS:
COUNTY OF MARION)

Subscribed and sworn to before me this 28 day of January, 1977.

/s/ Barbara F. Albright
Notary Public

My commission expires November 26, 1978

Supplemental Affidavit

No. 74 030 070 NP

SUPPLEMENTAL AFFIDAVIT

JEROME M. MAAS, M.D., being sworn, deposes and says:

1. I reside in Indianapolis, Indiana, and am a physician duly licensed to practice medicine in the States of Indiana and Wisconsin.

2. I am a former employee of Eli Lilly and Company ("Lilly"), having retired in April, 1975, and am presently a consultant to Lilly.

3. I am a member of the following professional organizations:

(a) American College of Obstetricians and Gynecologists (Fellow);

(b) U.S. International Foundation for Studies in Reproduction, Inc.;

(c) New York Academy of Science;

(d) Southern Obstetrics and Gynecologic Seminar, Inc.;

(e) American Society for the Study of Sterility;

(f) International Federation of Gynecology and Obstetrics;

(g) International Fertility Association;

(h) Pacific Coast Fertility Society.

4. I am familiar with the facts in this action and make this Supplemental Affidavit in Support of Defendants' Joint Motion for Partial Summary Judgment and pursuant to GCR 1963, Rules 117.2 and 117.3. I have personal knowledge of the facts recited herein and, if

sworn as a witness in this case, would be competent to testify thereto.

5. On the basis of my professional experience, I am familiar with the various medications used for the treatment of complication of pregnancy (i.e., threatened or habitual abortion, premature labor and pregnancy complicated by diabetes) between the years 1947 and 1964.

6. Six employees of Eli Lilly and Company, Betty DeHart, William Engle, Lila James, David May, Magdalene Pride and William Reece, reviewed the *American Druggist Blue Books*, the *Drug Topics Red Books*, and *The Modern Drug Encyclopedia* and *Therapeutic Indexes* for the years 1947 through 1964, to identify companies who offered estrogenic preparations for sale to physicians, pharmacists and wholesalers during these years. The *Blue Book* and the *Red Book* are standard references intended primarily for use by physicians, pharmacists and wholesalers in ordering drug products. The products are listed in alphabetical order and information on prices, dosage sizes and trade names of the drugs and their manufacturers is included. The *Blue Book* is published by the Hearst Corporation, New York, New York, 10019. The *Red Book* is published by Medical Economics Co., Oradel, New Jersey, 07649. Prior to 1970, it was published by Topics Publishing Co., Inc., New York, New York. The *Modern Drug Encyclopedia* contains detailed information on thousands of drugs, including their uses, and also lists some of their manufacturers and their trade names. It is currently published by the Yorke Medical Group of the Dun-Donnelly Publishing Corporation, New York, New York.

In addition to these three sources, the above named Lilly employees have reviewed the Sixth, Seventh and Eighth Editions of *The Merck Indexes* (Encyclopedia of Chemicals and Drugs) published in the years 1952, 1960,

and 1968 and the *Physicians' Desk Reference* for the years 1950-1964. *The Merck Index* is a standard reference which includes the exact chemical composition of thousands of individual substances, as well as some information on their history, uses, and trade names under which they were sold. It is published by Merck & Co., Rahway, New Jersey. The *Physicians' Desk Reference* is also a standard reference which contains information on drugs provided by their manufacturers. It is published by Medical Economics Company, a Division of Litton Industries, Inc. at Oradel, New Jersey.

The companies listed in these standard references sell their products with their labels to physicians, pharmacists, and wholesalers. These publications were distributed nationally, including the State of Michigan. They are voluminous and it would be unreasonable to attach them as exhibits. For instance the 1952 *Blue Book* consists of 704 pages, and the 1951-52 *Red Book* consists of 576 pages.

I have personally reviewed the references listed above for several of the years involved and am familiar with the information contained therein.

7. During the years 1947 through 1964 over 300 companies manufactured DES, diethylstilbestrol dipropionate and dienestrol. These synthetic estrogens which could have been used in complications of pregnancy are listed in these standard references as being offered for sale to physicians, pharmacists and wholesalers.

8. Of these over 300 manufacturers, at least 200 produced the above named synthetic estrogens in dosage sizes of 25 mg. or larger of diethylstilbestrol and diethylstilbestrol dipropionate or 10 mg. or larger of dienestrol.

Supplemental Affidavit

9. In addition to the three synthetic estrogens listed above, a wide variety of other estrogenic preparations including natural estrogens were indicated for use in complications of pregnancy. A preliminary review of the above standard references revealed the manufacturers and their products as listed in Exhibit A.

10. Not including the trade names of the *Abel* defendants, dienestrol products by distinctive trade names. (See Exhibit B, attached.)

In addition, there were other trade names for other synthetic estrogen products such as hexestrogen for hexestrol, stilphostrol for diethylstilbestrol diphosphate, and bestrocaps for benzestrol.

Dated: March 21st, 1977.

/s/ Jerome M. Maas, M.D.
Jerome M. Maas, M.D.

STATE OF INDIANA)
) ss:
COUNTY OF MARION)

Subscribed and sworn to before me, a Notary Public in and for the State of Indiana, County of Marion, this 21st day of March, 1977.

/s/ Dorothy L. Lewis
Notary Public

My Commission Expires: (Illegible)

L. Excerpts of Questionnaires of Plaintiffs filed in the Circuit Court for the County of Wayne

1. State:

(a) Your correct full name:

Sharon Barbara Beckler

* * *

4. State in chronological order the full address for each residence at which you have resided for thirty (30) days or more and the date each such residency was commenced and terminated.

6112 Elm Street, Morton Grove, Illinois 1954-1972 (Sept. 9, 1972)

143 Almendral Ave., Atherton Ca. Sept. 1977-March 1973

225 Olds Spanish Trail, Portola Valley, Ca. March 1973-June 1973

8920 Denton Road, Apt. #1, Belleville, Mi. (June 1973-August, 1974)

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. O. M. Simon, 2020 S. Ashland Ave., Chicago, Il.

17. State the name and address of all pharmacies through which your mother purchased DES.

Shots were given in the Doctor's office twice weekly from October, 1950 to April, 1951.

* * *

1. State:

(a) Your correct full name:

BARBARA FAYE (ne RUMBLE) BURMEISTER

* * *

4. State in chronological order the full address for each residence at which you have resided for thirty (30) days or more and the date each such residency was commenced and terminated.

1473 Burke NE, Apt. D, Grand Rapids, MI 11/72 - present

Glenview Naval Air Station, Glenview, Ill. 11/71 - 10/72

525 Livingston, Grand Rapids, Michigan 8/71 - 11/71

103 Helbourne, Grand Rapids, Michigan 6/71 - 8/71

624 Three Mile Rd, NE, Grand Rapids, MI 12/68 - 6/71

Fantasy Ridge, Mayfield, Michigan 8/65 - 12/68

423 West 11th Street, Traverse City, MI 3/65 - 8/65

203 West 11th Street, Traverse City, MI 10/63 - 3/65

6600 Longacres Dr., Sandy Springs, Georgia 4/63 - 9/63

Boughey Hill, Traverse City, Michigan 12/62 - 4/63

Interlochen Arts Academy, Interlochen, MI 8/62 - 12/62

520-1/2 South Union St., Traverse City, MI 9/61 - 7/62

3776 Vineville Ave., Macon, Georgia 8/60 - 8/61

187 Lokchapee Dr., Macon, Georgia 10/53 - 8/60

* * *

14. As to your mother and father, state:

(a) Their present names and address;

(b) Their names and addresses when your mother was pregnant with you;

(c) The inclusive dates of that pregnancy and whether or not the pregnancy was full term;

(d) If deceased, state the date, place and cause of your mother's and father's deaths.

(a) Mrs. Bessie Ivey McGrew, 624 Three Mile Rd. NE Grand Rapids, Michigan 49505

Paul M. Rumble, 3313 Hallwood Circle, Macon, Georgia

(b) Mr. and Mrs. Paul M. Rumble, 187 Lokchapee Drive, Macon, GA

(c) January, 1953 to October 13, 1953; full term

(d) Not applicable, both still living

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Evelyn Swilling (Mrs. Raymond Suarez)
844 Park View Drive, Macon, Georgia 31201

17. State the name and address of all pharmacies through which your mother purchased DES.

Chichester's Ingleside Pharmacy, 3051 Vineville, Macon, GA

* * *

1. State:

(a) Your correct full name:

Donna Teresa Coppess (Hursch)

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Philip Reynolds - Los Angeles, California - Good Samaritan Hospital - 1212 Chakee, L.A.

17. State the name and address of all pharmacies through which your mother purchased DES.

?

* * *

1. State:

(a) Your correct full name:

Ivy Sue Grossman

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Joseph Gross Cleveland, Ohio

17. State the name and address of all pharmacies through which your mother purchased DES.

?

* * *

1. State:

(a) Your correct full name:

Barbara Gaye Herzoff

* * *

4. State in chronological order the full address for each residence at which you have resided for thirty (30) days or more and the date each such residency was commenced and terminated.

1327 N. 54th St., Omaha Nebraska

16249 Hilton Rd., Southfield

25785 Catalina Rd., Southfield 5-64-present

26 Bloomfield Terrace, Pontiac 8-74 thru 11-74

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Donald C. Vraman 36th & Dodge Omaha, Nebr.

17. State the name and address of all pharmacies through which your mother purchased DES.

Seward & Lee Pharmacy 216th & Dodge, Omaha, Nebr.

* * *

1. State:

(a) Your correct full name:

Lois Jean Hill

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

H. W. Erving, M.D. The Elizabeth Steel Magee Hospital, Pittsburg, PA

17. State the name and address of all pharmacies through which your mother purchased DES.

? Might have been in Cheswick, PA.

* * *

1. State:

(a) Your correct full name:

Sherill Marise Kurland

* * *

1. State:

(a) Your correct full name:

Sherry Lynn (Maiden Strumeyer) Hunt

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. J. J. Squire - 35 E. 61st St., New York, New York

17. State the name and address of all pharmacies through which your mother purchased DES.

Grunswalls Pharmacy, E. 79th St., N.Y., N.Y.

* * *

1. State:

(a) Your correct full name:

Sheridan Lynn Hudson

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Harold C. Mach, Phoenix, Arizona

17. State the name and address of all pharmacies through which your mother purchased DES.

(Illegible) Toledo, Ohio

(Illegible) 3145 Nebraska, Toledo, Ohio 43607

* * *

1. State:

(a) Your correct full name:

Mary Lou Warnke.

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. A. J. Tatelbaum - 1600 East Ave., Rochester, New York

Miami Beach, Florida

17. State the name and address of all pharmacies through which your mother purchased DES.

Monroe Pharmacy - Rochester, New York

* * *

1. State:

(a) Your correct full name:

Inez Michelle Shearer

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Charles Weitzman Eastern Pkway, Bklyn., N.Y.

17. State the name and address of all pharmacies through which your mother purchased DES.

Drugstore Corner of Howard Ave. & St. Johns Place, Bklyn, N.Y.

* * *

1. State:

(a) Your correct full name:

Susan Ellen Yenofsky

* * *

16. State the name and address of the doctor who placed your mother under a program of intake of DES.

Dr. Samuel Siddell (deceased) Boston, Mass.

17. State the name and address of all pharmacies through which your mother purchased DES.

Wellington Hill Drugs - ? Bluehill Ave. - Dorchester, Mass.

Grove Hill Pharmacy - ? Bluehill Ave. - Dorchester, Mass.

(Both are no longer in business) No records available

* * *

M. Defendants' Brief on Appeal, Regarding History of Synthetic Estrogens, Supreme Court of Michigan (excerpt pp. 1-9)

STATEMENT OF FACTS

In their initial complaint (Appellants' Appendix, at 3a-39a) [hereinafter references to Appellants' Appendix will be designated in the form (3a-39a)], the female plaintiffs in *Abel* claimed to have suffered injury to their reproductive tracts,[1] through exposure to one of *seven* synthetic estrogens prescribed for, and taken by, their mothers during pregnancy (5a), to assist the mother in maintaining the pregnancy (5a). Although plaintiffs' counsel conceded that little investigation had been undertaken (272a-276a), by the time of filing of the *Abel* Plaintiffs' Fourteenth Amended Complaint, the "selection of possible injury-causing drugs" had mysteriously decreased from seven to three: (1) diethylstilbestrol (DES); (2) dienestrol; and (3) diethylstilbestrol dipropionate (DSD) (318a-319a).

Each of the three drugs, DES, dienestrol and DSD, presently involved in this lawsuit is a chemically distinct compound (297a, 428a, 437a-439a). Only two of the defendants ever marketed more than one of them during the alleged period in question (1947 to 1954) (483a, 92a, 93a-96a). Of the other 14 defendants, 11 marketed only DES (483a),

---

[1]Two of the *Abel* plaintiffs were alleged to have cancer, and the remaining 140 apparently have vaginal adenosis, the presence of normal glandular tissue in the vagina which is usually only found in the endocervix. From October 27 through November 20, 1980, the *Abel* plaintiffs' trial counsel tried a DES-adenosis case, *Keil v. Eli Lilly & Co.*, No. 570997 (E.D. Mich. Nov. 20, 1980) and the jury, in answering special interrogatories, found that Lilly was NOT negligent. In relation to the plaintiff's injuries in *Keil*, trial counsel did not request Judge Charles W. Joiner to submit any damage issue that adenosis is, was or may be precancerous (487a-488a). The *Keil* case is the only DES-adenosis case that has been tried.

two marketed only dienestrol (483a, 83a, 235a), and one marketed only DSD (483a, 86a-88a).

In the late 1920's, natural estrogens were available for human use (125a), and were prescribed to treat the symptoms of menopause (125a), a use not involved in this lawsuit (318a-319a). Although the natural estrogens were "proven" to be "quite effective and safe in the treatment of menopausal symptoms" (128a), they were not effective orally and had to be given by painful injection in an oil solution in the buttocks, which often caused abscesses (125a-126a, 252a). In addition, natural estrogens were "very expensive" (251a); one such natural estrogen was 300 times more expensive than DES. In the late 1930's, researchers began to develop different synthetic (man-made) estrogens, including the three different drugs alleged to be involved in this lawsuit.

A. Diethylstilbestrol (DES).

In the late 1930's, an English chemist, Dr. E. C. Dodds, first synthesized DES (125a), the molecular structure and configuration of which has remained the same since it was first developed. Although the active ingredient in all DES must be chemically the same, the chemical ingredients added to DES by the individual companies to facilitate the actual manufacture of tablets or other dosage forms of the drug can and do vary substantially. Thus, although the chemical composition of DES may meet uniform chemical standards, the actual dosage forms are not identical.

Dr. Dodds did not patent the drug, which "meant that anybody who wanted to could market it" (125a). But before there could be any marketing of DES in the United States, a New Drug Application (NDA) for the drug had to be approved by the Drug Division of the Federal Food and Drug Administration (FDA) pursuant to the statutory

requirements imposed by the Federal Food, Drug and Cosmetic Act of 1938 (249a).

Dr. Theodore G. Klumpp was the Chief of the FDA's Drug Division in 1941 (248a) when DES was first approved for a use (an "indication") in the United States (260a). It was Dr. Klumpp's Division that was responsible for making the final recommendation to the Commissioner of the FDA regarding the approval or non-approval of 1941 NDA's for DES. Each NDA had to include data on the chemical identity of the drug, quality control data on methods of manufacture, data on clinical studies (reports on human use of the drug) to establish the safety of the drug and proposed labeling (249a-250a). As to clinical studies, the FDA wanted to review reports "made by responsible and, not infrequently, outstanding authorities in the given field of therapy" (250a).

By the end of 1940, according to Dr. Klumpp, 10 firms had 10 separate NDA's on file with the FDA seeking approval to market DES (252a) for treatment of menopausal symptoms, senile vaginitis, postpartum lactation and gonorrheal vaginitis, uses which are not involved in this lawsuit (125a-128a). In light of these multiple submissions, Dr. Klumpp and others at the FDA met before December 30, 1940, and in relation to DES decided: (a) that "it would be in the public interest to have all this clinical material pooled" (254a); and (b) to refer to the pooled material "as the master file as it had been in the sulfathiazole [a drug approved by the FDA prior to DES] case" (254a, 250a-251a). The FDA conveyed this decision to the drug companies through a Mr. Carson Frailey, who reported back to the FDA that the manufacturers "didn't like the idea [of pooling data] one bit" (254a). The FDA stood firm and at a meeting on December 30, 1940, demanded that the companies file joint clinical data (263a).

Because "pooling" was thus required and demanded by the FDA for DES (254a), the companies eventually acquiesced, and held two additional meetings (145a, 135a). To comply with the FDA's "pooling" requirement, the companies agreed to form a "Small Committee" to coordinate the gathering of clinical data for the FDA (134a-135a).

The FDA made its own independent investigation (265a-267a). It contacted clinical investigators and personally interviewed them to learn their opinions on marketing DES (265a-267a), and it relied on the studies and opinions of outside experts (268a). Also, Dr. Klumpp personally followed "whatever medical literature" there was on the subject of DES (259a). The FDA did not itself conduct any clinical or animal studies, because by law that agency was not allowed to do so (268a).

In May, 1941, the pooled "master file" was formally submitted to the FDA (138a-139a). Eleven of the sixteen defendants in *Abel* did not participate in this submission (144a-145a); conversely some of the companies who joined in the submission are not joined in *Abel* (144a-145a). As part of the "master file", 5,300 cases were submitted to the FDA (139a). According to Dr. Klumpp's undisputed testimony, the "quality" of the joint submission was a high at that time, and the quantity was greater than any previous submission (261a). The FDA wanted the companies to comply with the United States Pharmacopeia (USP) to make certain that the active ingredient in each company's DES met uniform chemical standards (146a, 262a). Therefore, the FDA directed the companies to comply with USP standards (146a-148a). The FDA concluded, after further evaluation (262a), that DES was safe and effective (262a). The separate NDAs for DES were approved in 1941, and are still approved, for uses of the drug which are not involved in this lawsuit. The Small Committee was dissolved in 1941 (139a, 436a).

B. Diethylstilbestrol Dipropionate (DSD).

Defendant Blue Line first marketed DSD in June, 1943 (87a). DSD was a patented drug (437a-439a). DSD is *not* DES. In 1951, Blue Line sought FDA approval to market DSD for use in complications of pregnancy (165a). Blue Line stated in informational material that DSD had a slower absorption rate, more potency and greater duration of effect than DES (89a). Blue Line never represented DSD as a "generic equivalent" of DES (238a). Defendant Cole Pharmacal was the only other *Abel* defendant who ever marketed DSD.

C. Dienestrol.

Dienestrol was developed in England in the late 1930's by a group headed by Dr. Dodds, who also synthesized DES (232a, 233a). Dienestrol, which is a chemically distinct drug, appeared to have an advantage over DES because it was reported to induce fewer cases of nausea in patients taking it (233a)

Defendant White Laboratories filed an NDA for dienestrol in June, 1946, for clinical uses unrelated to the state of pregnancy. It had not participated in the 1941 activities of the Small Committee with respect to DES (234a), and it did not contact any other company for any information respecting DES (233a). In 1950, White filed a supplemental NDA for permission to market dienestrol for treatment of certain pregnancy disorders, submitting clinical data related only to studies of dienestrol, not DES (472a-476a). Dienestrol was marketed by only two other *Abel* defendants: Cole Pharmacal and Central Pharmacal (83a, 93a). As is thoroughly documented in the separate brief filed by defendant White Laboratories, Dienestrol, DES and DSD are not generic equivalents.

D. Submissions To The FDA For Uses Of Synthetic Estrogens In Problem Pregnancies.

The pioneers in the field of using natural and synthetic estrogens for women who were threatening to abort or who had a history of miscarriage were Drs. George and Olive Smith, at Harvard (140a), and Dr. Priscilla White of the Joslin Clinic in Boston, the first clinic to specialize in the treatment of diabetes (141a). "They [the Smiths] were in the absolute top bracket of researchers on endocrine problems" (140a), and Dr. Priscilla White was "one of the very top authorities" in the treatment of pregnant diabetics (141a). Dr. Don Carlos Hines, Lilly's medical monitor for DES from 1939 to 1952, has testified that by 1947, DES "had been used for some seven years . . ." for accidents of pregnancy ". . . especially in the case of [Drs. George and Olive] Smith and [Priscilla] White. . . ." (151a). "[Their] patients had been followed . . . for six years so we felt that this material was quite an adequate experience to establish both efficacy and safety. . . . I doubt . . . if they have discovered an animal model that in any way parallels the accidents of human pregnancy" (151a).

From 1947 on, at various times various *Abel* defendants independently filed applications with the FDA to market different synthetic estrogens for uses in accidents of pregnancy: Abbott, May 15, 1947; Blue Line, May 7, 1951; Lilly, April 15, 1947; McNeil, September 10, 1948; Rexall, October 18, 1948; Squibb, April 28, 1947; and White, January 11, 1950 (440a-441a, 165a, 439a-440a, 471a-472a, 229a, 237a, 476a-477a). Although other companies variously filed their own NDA's regarding the use of synthetic estrogens in the treatment of some accidents of pregnancy, two *Abel* defendants, Burroughs Wellcome and Vale, *never* requested FDA approval to sell any synthetic estrogen for use in pregnancy, and never even sold a synthetic estrogen in a dosage size most compatible with use in complications of pregnancy (228a, 246a).

Unlike 1941 when the FDA required the "master file" of clinical data for DES (254a), in 1947 and thereafter: (a) no defendant participated in a "master file" of clinical data for a synthetic estrogen for use in pregnancy (148a); and (b) neither the labeling (441a-467a) nor the directions for use (441a-471a) were uniform in regard to the use of a synthetic estrogen for pregnant women. Companies making NDA filings for use of DES during pregnancy were also required to submit data separate and distinct from the showing that had been made earlier in seeking approval to market DES for different uses pursuant to the statutory mandate that different data be supplied for each new use. *See*, 21 U.S.C. § 355(d) (1970); 21 C.F.R. § 310.3 (1980), promulgated Dec. 22, 1938, 3 Fed. Reg. 3161-62 (1938). Moreover, eleven of the *Abel* defendants used trade names in marketing DES for uses in accidents of pregnancy (484a-485a), such as McNeil's "Engestic" (90a-91a). In addition, 66 different trade names were used from 1947-1964 by companies who are not defendants in this action, as a part of the marketing of DES, dienestrol and DSD (294a-295a). Companies did not offer their products in the same dosage forms (83a, 87a, 234a). Defendants' product brochures were not the same (441a-467a).

The record in *Abel* contains (a) no evidence of joint efforts among the manufacturers of synthetic estrogens following the 1941 FDA-mandated submission for the uses not involved in this lawsuit, and (b) no evidence that there were joint efforts or communications in any way, form or manner between any *Abel* defendants concerning the use of synthetic estrogens in treating certain accidents of pregnancy. This is amply demonstrated by the testimony of Dr. Hines, the Chairman of the Small Committee which compiled the "master file" in 1941 (96a, 237a).

At least by 1951, the FDA had determined, on an individual company by company basis, that DES was no

longer a "new drug" within the meaning of the Federal Food, Drug and Cosmetic Act, and therefore that the drug was "generally recognized . . . as safe" (479a-482a). After that time, DES could be marketed by any manufacturer complying with good manufacturing standards; but any such manufacturer was *not* required to file an NDA with, or obtain approval of, the FDA. *See* Federal Food, Drug and Cosmetic Act, ch. 675, § 201, 52 Stat. 1042 (1938) (current version at 21 U.S.C. § 321).

Between 1947 and 1964, over 300 companies manufactured synthetic estrogens which could have been used in complications of pregnancy (278a-280a, 291a). Furthermore, because the companies marketed their different products over different periods of time during 1947 to 1964, many *Abel* plaintiffs could not have been exposed to the products of many defendants. For example, because defendant Cole Pharmacal Company first manufactured its 25 mg. DES (which could have been used for complications of pregnancy) on May 22, 1951 (95a), over 30 *Abel* plaintiffs who were born prior to that date could not have been exposed *in utero* to Cole Pharmacal's 25 mg. DES (166a-227a).

E. The Herbst Publication.

In 1971, 34 years after any of the drugs named in *Abel* were first used to treat pregnant women, Dr. Arthur Herbst, Dr. Howard Ulfelder, and several other physicians at Harvard Medical School published a paper, 284 New Eng. J. Med. 878 (April 22, 1971), that disclosed *"for the first time"* a statistical association (not a cause and effect relationship) between the use of DES in pregnancy and a form of gynecologic cancer (clear cell adenocarcinoma) in some of the female offspring of pregnant women. *FDA Drug Bulletin*, November, 1971.

More relevant, however, as to almost every *Abel* plaintiff, Herbst also reported the existence of "*benign adenosis* of the vagina" in the group of patients examined. Adenosis is the presence of normal, columnar cells (glandular tissue) in the vagina instead of its usual location in the endocervix. It is, as Herbst reported in 1971, benign. Based on the *Abel* Plaintiffs' Fourteenth Amended Complaint, it appears that all but two of the 142 female plaintiffs claim to have adenosis.

F. The Abel Proceedings.

The majority of the female plaintiffs originally alleged that they could not identify (a) the drug that was taken by their mothers, or (b) the manufacturer who made the alleged injury-causing drug. Plaintiffs, therefore, alleged and urged that all defendants should be held jointly and severally liable. Defendants responded by filing a Motion for Summary Judgment pursuant to GCR 1963, 117.2(1), on December 23, 1974,[2] which was denied by the Honorable Thomas Roumell on March 10, 1975. Although the Judge stated his reluctance to grant summary judgment at the "early stage of the proceedings", his Opinion and Order provided that defendants' motion for summary judgment could "be raised again at a later time" (48a). Recognizing the need to focus on the factual basis of plaintiffs' claims, the Court ordered that discovery be undertaken to determine if there was any factual basis for plaintiffs' claims of concert of action or other forms of "collective liability" (61a-63a).

Discovery proceeded until, two years later, all parties voluntarily agreed before the trial court that discovery on the issues of multiple-defendant liability had concluded

---

[2]For a summary of the law on product and manufacturer identification, *see* note 8, *infra*.

N. Portions of Defendant E. R. Squibb & Sons, Inc.'s Appendix, Supreme Court of Michigan

124a *Deposition of Don Carlos Hines*

No. 74 030 070 NP

DEPOSITION OF DON CARLOS HINES

March 1, 1976

• • •

[16] Q. Would you describe for us, Dr. Hines, the basic duties of a monitor of a drug such as DES; what were your responsibilities?

MR. CHARFOOS: Counsel, can we get a date reference, please?

MR. BAUER: When he took over in 1940.

MR. CHARFOOS: Fine.

THE WITNESS: When I took over in 1940, perhaps his first duty was to know what the drug was all about. He had to understand the diseases for which it was proposed for use or was being used. He had to know something about the drug itself. It was part of his duty to keep up with everything that was published, to become acquainted with the investigators who were considered to be the leading authorities, both on the diseases that were being treated by that drug, and on the drug itself, so that he was really supposed to know everything that was known about the drug and what it was used for.

MR. BAUER: Q. Would that encompass talking with leading doctors and scientists around the country about the particular drug?

A. It would include that. It would include going to meetings where the papers were presented on the disease or the drug and keeping up with the published literature everywhere.

• • •

[26] Q. All right. Let's get into the background and development of diethylstilbesterol. Where was the sub-

stance first developed, Dr. Hines? A. It was developed in England.

Q. And do you remember by whom? A. Well, the man who is generally given credit for it is named E. C. Dodds, D-o-d-d-s. He's a chemist.

Q. And do you know who his co-workers were, or any of them? A. There are several of them. I don't —I don't recall their [27] names at the moment.

Q. All right. Was this a patented drug? A. No. Dr. Dodds made the decision not to patent it but to throw it into the public domain.

Q. And what consequences did that have in the pharmaceutical industry? A. That meant that anybody who wanted to could market it and a great many people did want to.

Q. What was the initial theory of the use of DES; why would it be beneficial and helpful and for what particular reasons, I mean conditions? A. Well, I believe the first thought was for use in the treatment of menopausal symptoms because these symptoms were believed to be associated with a deficiency of estrogen.

* * *

[28] Q. How did DES fit into the picture as far as treating women that were going through the menopause was concerned? A. Well the natural estrogens had been available for this sort of use for almost ten years, about ten years. The first natural estrogen to be isolated was estrone, and when it was discovered how to isolate it and purify it, it was available; but it was not a, very effective when given by mouth because everything that is absorbed from the gastrointestinal tract has to go through the liver, and the liver just took this estrone out so that it didn't get through the liver and to the systemic organization so that it could act, so it had to be given by injection.

And since it wasn't soluble in water, it had to be given [29] in oil solution.

Q. Where would they normally give the injection? A. The usual place was the buttocks.

Q. Did it cause some uncomfort? A. Well, it could, and then there were—you had to give it at least once a week, and after you had two or three cubic centimeters of oil put in your buttocks every week for two or three years, you had a lot of oil in there and it could be pretty sore and painful. The oil is very slowly absorbed. It's a foreign substance.

Q. Well, then, when this synthetic estrogen, DES, was developed, was that then used to treat menopausal women? A. Yes, indeed. This was one of the first ideas. Now, I should add that when you could give sufficient dosage, this treatment with natural estrogens was extremely effective and it brought relief to a great many women from what was a, a very disturbing and often disabling combination of symptoms. The point about diethylstilbestrol—well, there were two points: The first was that it was well absorbed when taken by mouth so that the patient could be relieved of these weekly trips and the injections with the undesirable accumulations of oil. And the other feature was that whereas the injections of the natural estrogens were rather expensive, quite expensive, in fact the diethylstilbestrol was quite inexpensive.

* * *

[34] Q. Dr. Hines, we are continuing again. Would you tell us some of the other uses that DES was put to when it was developed beside helping women with menopausal symptoms?

* * *

A. When, when estrogen is no longer available, the epithelium, that is the surface coating of cells in the vagina, atrophies and as a result of this atrophy, it is susceptible to infection. It is uncomfortable, it itches, and so on.

• • •

Then it was used next in the treatment of vaginitis, that is inflammation of the vagina, in little girls due to [35] gonorrhea. In the adult woman, gonorrhea does not attack the lining of the vagina; it goes farther up and attacks the uterus and the uterine tubes. But little girls who are, as yet don't have a very large supply of estrogen, the mucous membrane, that is the lining, is in a relatively undeveloped state, somewhat different from that in the menopause, but it is undeveloped, and experts in this subject knew, knew that there was this difference between the little girl and the grown woman and they were, one of them or some of them were imaginative enough to picture that if they could temporarily produce the adult stage in the vagina, that the gonococcus might die out and this turned out to be the case. • • •

• • •

Then very shortly after that, it began to be used in fairly large doses and the treatment of what was called functional uterine bleeding. This was irregular, unexpected bleeding that was due to usually to an imbalance in the hormones, and it was found that if you could give a good sharp jolt of estrogen in pretty large quantities that this just stopped that [36] kind of thing and then the next cycle, the next ovarian cycle, things would usually be on the right track. So these were the four initial uses.

Q. When was DES used to stop engorgement of breasts? A. That was another one. I should have put

that before the functional uterine bleeding. That was one of the very early ones.

Q. Explain that for us, please. A. When women don't nurse their babies, their breasts become engorged and painful. So that it was found and I don't recall how anybody thought of this, but they did pretty early, and if you gave rather large doses for a week, it would not, it would stop this painful engorgement, cut it off quite sharply.

* * *

[43] Q. Dr. Hines, Lilly at some point made the decision to proceed with testing of Diethylstilbestrol on human beings; is that correct? A. That's right.

Q. And at that time what were the reasons that Lilly felt it was safe to proceed with the initial clinical trial or testing program for DES? A. You mean in 1939 when they started?

Q. Yeah. A. There had been rather extensive work on animals and this was—a lot of this was repeated in the Lilly pharmacology laboratory. And they did not discover any adverse effects when it could be used in—when it was used in doses that were pharmacologically effective in the animal being tested. In addition to that there had already been quite a little human trial in Great Britain so that this was not a pioneering venture in the use of the drug in human beings. There are quite a few publications in Britain and already by the—oh, by the first, by the first half of 1939.

Q. What role did the information that you had concerning the use of natural estrogens in women prior to 1939 have in Lilly's making the decision to proceed with testing of DES? A. Well, it was already evident that the natural estrogens had proven quite effective and safe in the treatment of menopausal symptoms and that it

was—that there, that was the main thing at that time because with the natural estrogens at that time, [44] it was rather difficult to give very large doses, those that were much larger than what you might call physiological. The question then was since there is a different chemistry, does Diethylstilbestrol in fact duplicate the action of the natural estrogens both in the desirable effects and in the potential harmful effects. So that there was a certain amount of evidence, certainly there was the evidence from the animals that the effects were identical. Then there was the results in human trials in Great Britain that had not disclosed any differences in the effects of Diethylstilbestrol from the natural estrogens. So although naturally we kept our eyes out, it looked as if we had something that at least, the least you could say was that it did not pose any unreasonable hazard.

* * *

[53] Q. All right. Skipping ahead just slightly in our story, but what was the date that the FDA approved the release of Diethylstilbestrol as a new drug? A. Well, as I said they didn't approve it.

Q. When did they— A. They permitted it to become effective.

Q. When was that, do you know? A. About the middle of June, middle of September in 1941.

Q. Well, now, let's talk about the scope of your clinical trial as it had developed at that time. Can you give us an idea as to how large this clinical trial was, how many different cases were involved in it? A. At the time that, that Diethylstilbestrol went on the market, there were reports of available actually of about 8,000 patients. I think about 1800 of them had received the drug for menopausal symptoms for a period of at least six months and some of them for more than two years. In fairly early 1940 we

have reports, received reports from investigators on almost 5,000, I think it was, it was something between 4500 and 5,000 patients I think, well, maybe a thousand physicians altogether.

[54] Q. How large was this clinical trial for DES in comparison with an average clinical trial submission for other drugs? A. Well, it was more massive in all respects in both scope, size, number of patients, and in depth, thoroughness of the—

Q. Can you give me an idea of approximately— A. The average might be several hundred.

Q. For other drugs? A. Yes. This was by all orders the most comprehensive clinical investigation that had ever been undertaken up to that time.

Q. Now, you have mentioned the word ampule. Maybe we should discuss briefly the forms in which DES was marketed. Would you tell us the different forms and what they were called? A. Well, it was marketed in tablets and of various strengths. And some companies had special coatings for certain purposes. Then it was marketed in ampules which are glass—oh, it was also, for oral administration, it was also I think by one company, and I don't know for how long, it was dissolved in oil and the oil was encapsulated into a flat gelatin capsule instead of a tablet. Then it was available in suppositories which were, in which the drug was incorporated in a soft gelatin base that dissolved slowly in contact with moisture. This was for, particularly for the treatment of vaginitis, atrophic vaginitis in menopausal women. Then it was marketed in ampules, * * *.

* * *

[60] Q. . . . were there other pharmaceutical companies that were working on the development of DES? A. Oh, yes, they certainly were.

Q. That was because it was an unpatented drug? A. That's exactly why it was. The other factor was that it looked like a very useful addition to the doctors' array of drugs.

* * *

Q. All right. Toward the end of 1940, did you receive a request from the FDA to meet with them and other companies in Washington? A. Yes, I did.

Q. Can you tell us briefly how that came about, what were the circumstances of that request by the FDA? A. I don't remember how and what form the communication came, but they requested that a physician handling the drug come to a meeting in Washington with the Food and Drug Administration and then it would be, our understanding [61] was that they were asking all the companies who had filed new drug applications to send representatives. That's all I knew before I went to the meeting.

* * *

Q. Do you recall or can you tell us the date that you and representatives of other drug companies that had filed new drug applications for Stilbestrol met with the FDA in Washington, D.C.? A. That was December 30, 1940.

* * *

[64] Q. As a result of the meeting with the Government on December 30, 1940, did Lilly withdraw its pending NDA at that time in order to collect additional clinical information? A. This happened at about that time but I'm not very clear as to the direct relationship.

Q. Tell us what happened at that time. A. Well, we did at the suggestion of the Food and Drug Administration, we did withdraw our New Drug Application.

Q. With what idea, of submitting it later? [65] A. Later, yes.

Q. With additional material? A. Yes. Now, I may say that the—when I—this may be a slight, to an extent a repetition of what I have already said, but I think it should be made clear, that there was a great deal of concern in the Food and Drug Administration because of the very strong opposition to the marketing of Stilbestrol by a few clinical investigators.

Q. And do you happen to remember the names of those clinical investigators that seemed to be in opposition to the marketing of DES? A. There were four and they were all in New York City. The one who was best known in academic circles was Dr. Efram Shorr.

Q. Spell that last name. A. S-h-o-double-r. I don't think there's a "c" in it. I think it's just S-h-o-double-r. And Dr. Samuel Geist, G-e-i-s-t, Dr. Salmon, S-a-l-m-o-n. I don't remember his first name. And then there was a Dr. Raphael Kurzrok, K-u-r-z-r-o-k.

Q. Did you say all of these gentlemen were from New York City? A. They all are New York City.

Q. They had apparently taken an initial position in opposition to the marketing of Diethylstilbestrol? A. Yes, very strong one. * * *

* * *

[71] Q. Can you tell us, Dr. Hines, why, at least as far as Lilly was concerned, the company decided to proceed with this request by the government for joint admission of the clinical trial data? A. Well, at a meeting late in January, again called by the Food and Drug Administration, they made it quite clear that the companies had better get together. A lot of this was leaving you to draw your own conclusions, but the message came through to me anyway loud and clear that if you didn't

go in you might find yourself right out in left field and that you might be delayed in having your application permitted to become effective.

Q. How long was it after the initial meeting held by the FDA on December 30, 1940 that Lilly at least agreed to go ahead and submit the clinical data jointly with the other companies? A. About the first of February after another meeting, the second meeting that was called by the Food and Drug Administration at least indirectly suggested by them. That was held, I believe, on January the 28th, 1941 at—in Washington at the FDA office.

Q. Can you tell us briefly what happened at that meeting on January the 28th, 1941? A. They made it quite clear that they were pretty insistent on this joint clinical application, and they also made it clear that—what they wanted was the views of experts and they gave us a list of—they named the investigators from whom they wanted statements.

* * *

[75] A. I am quite sure that this is a copy of what I wrote at that time dated January 30th, 1941.

Q. 1941? A. 1941.

Q. Name the companies for the record. A. These are the companies that were represented. I don't suppose you are interested in the names of the doctors?

Q. No; just the companies. A. Eli Lilly, of course. Squibb, Winthrop, Merck, Abbott, Upjohn, Sharpe & Dohme; John Wyeth, Charles E. Frosst, that was a Canadian company, Ayerst, McKenna & Harrison, also a Canadian company. Those are the ones who were represented.

Q. Dr. Hines, tell us about the selection of this committee; how did it come about, who was on it, who was made chairman of it? A. All the—I'm starting with

what I think is a relevant starting point on page two of the memorandum.

"All the representatives were willing and anxious to follow the plan of filing a joint application with two exceptions. The representatives of Squibb could promise only that they would pool the data obtained since the last filing of their application. The matter—" I was not in a position, and I am speaking for myself, of course, because I made this report, which was an internal company report.

"I was not in a position to assure the group of our cooperation and stated so frankly. It was agreed that none of those joining the group for joint filing would file an application [76] previous to the filing of the joint application.

I was chosen temporary chairman of the meeting and despite my pointing out my possible inability to serve further was made permanent chairman of the meeting and of the committee which was there appointed for the purpose of actually getting together the material for submission."

The members of this committee were Dr. J. A. Morrell of Squibb; Dr. J. B. Rice of Winthrop, and Gifford Upjohn of the Upjohn Company.

Q. What was the name given to that committee, Dr. Hines? A. It was called the Small Committee.

Q. How did that name come about? Why was it called the Small Committee? A. Because it was four people and the whole group was ten.

Q. All right. Anything else about that meeting—
A. Yes.

Q. —that you might like to mention? A. Yes. I think it would be relevant.

"Following the meeting, the Small Committee met and outlined a detailed program for gathering the necessary information. This was expected to involve personal contact

with each of twenty-four men and groups in Boston, New York City, Philadelphia, Baltimore, Chicago, Madison, St. Louis and Rochester, Minnesota, the cities mentioned by Dr. Durrett as containing the key men. It was planned that the preliminary data would be submitted to me by March 1."

[77] Q. Even at this meeting where you were elected chairman of the Small Committee, as I understand it, you still at that time did not have the approval of Eli Lilly and Company to this proposal of the government, is that correct? A. That is correct.

* * *

Q. All right. Up to that time had any of the companies that were involved in this meeting with the government been in contact with Lilly concerning any joint efforts of developing or testing this product? A. Not to my knowledge.

Q. When is the first time that any joint effort was done in obtaining clinical trial data following these meetings with the government? A. The first suggestion that I ever heard of any joint endeavor on stilbestrol was what was proposed by Dr. Durrett on December 30th, 1940.

* * *

[82] Q. All right. There was another meeting then of the Small Committee, I believe you said, in March, March 24th and fifth of '41? A. Yes.

Q. Was that just the committee or did all of the companies that were— A. No—

Q. —participating? A. No. * * *

* * *

Q. All right. Why did the Small Committee meet on those dates and what did you discuss? [83] A.

Oh, by that time I had been able to get the material that had been submitted by March 1st, getting it together and organized and had—I believe also by that date I had prepared a piece of literature that I thought summarized the situation on stilbestrol, it would be suitable as a source of information on it for practitioners, and so we went over it with the Small Committee, that was the first exposure of the members of the Small Committee to the total of the data that had been collected so far. So we went over that on March 24th and they, I believe, a number of them also brought literature that they had prepared on the basis of what they knew about the drug and actually the total of the material submitted by the different companies all added up to the same thing. There wasn't any difference in the sort of experience that was reported to the different companies, so it was perfectly all right for them to do that on the basis of what had already been reported to them.

And we agreed that we thought this should be adequate. And I think it was at that time that we looked over the literature that the various company representatives prepared and they decided that our literature that I had prepared was—they would choose to recommend that the Food and Drug Administration use that as a model, or recommend that as a model.

Then the next day we went down to Washington and met with representatives of the Food and Drug Administration and we presented all of this to them.

* * *

[86] Q. I again have here the report that you wrote of the meeting on March 24th and 25th, 1941, which was dated March 28th, 1941, if you would care to look at it.

* * *

Q. Well, Dr. Hines, about how many cases had been collected from clinical investigators at that time that you were discussing [87] in March of 1941? A. Well, I think I can do best by reading something from here.

Q. All right. A. "The American literature now includes," that means published reports, ". . . now includes reports of the treatment of more than 2400 cases," that the data from the questionnaire included, this, of course, was the first questionnaire.

Q. Uh-huh. A. "The data from the questionnaire included about 5,000 cases, more than 1600 of which had received stilbestrol for periods of more than six months. No one had observed cumulative toxic effects from long administration. All investigators except three were in favor of the release of the drug by the Food and Drug Administration. These three were Drs. Ephraim Shorr, S. U. Geist and U. J. Salmon, all of New York City."

There was one further point. Naturally if the results were going to be pooled, the Food and Drug Administration had to be convinced that all of the reports were from the administration of the same substance. So that each company was asked to submit the data that established the identity and purity of the stilbestrol, and it was thought that the most expeditious way of presenting that was to have the information accompany the joint clinical report.

Q. Did you use the term "master file" in referring to the compilation of the joint clinical trial data? A. Yes, we called it the Master File.

[88] Q. All right. Was there anything else of significance about that meeting in March with the FDA by the Small Committee? A. They spelled out in great detail some of the exact procedures that were to be followed, that this joint clinical subject submission, something about that, and they made it quite clear that that is as far as anything joint would go, that each company had to make its own application, that would complete all of

the requirements and they had some technical requirements about making reference to the "Master File" and it is called "The Master File," it makes reference to previous applications and—

* * *

A. "The administration desired to receive a single master filing of the scientific data which would name the companies collaborating in their collection. Each application—" excuse me—". . . each applicant must then in his application, one, make suitable reference to the Master File. Two, make suitable reference to previous applications. Three, outline the process, outline the process of the manufacture of the drug. Four, establish the identity of the drug and, five, include copies of labels and overall promotional literature regardless * * *.

* * *

[91] THE WITNESS: There were something over a hundred physicians altogether who had used the drug. Of those that could really be considered experts in the field, I think there were approximately fifty, and that would leave it forty-six to four.

MR. BAUER: What happened after your meeting with the FDA in Washington in the latter part of March of 1941?

A. We made up the second questionnaire and sent it out. I think we covered that.

Q. Yes. Did you get information back concerning the questions that were posed in the second questionnaire? A. We certainly did.

Q. And did you correlate that information? A. I did.

Q. Was that information also submitted to the FDA? A. The formal Master File was sent in in the second

half of May and we made copies of it and sent copies to all of the companies that were in the joint file.

* * *

[94] Q. All right. When you submitted the formal or final Master File, can you tell us how many total cases you had at that time? A. As I remember, if you omit the possible duplication in Chicago, there were 5300 total cases and some 1600 had been in menopausal remedy who had been treated at least six months.

Q. Did you at that time submit some proposed labeling, as far as Lilly was concerned? A. We submitted—we had told all of the companies that—when I say "we told all of the companies," I mean our communication was through the medical people, that the—what had been the case at that time, that the Food and Drug Administration urged that the companies follow our literature as a model. And they emphasized particularly that the indications and dosage recommendations should be uniform for all companies, that they insisted on that.

Q. When you use the term "all of the companies," are you referring to the companies that had participated in the joint submission of clinical trial data? A. Yes.

Q. You are not talking about the whole industry? A. No, we couldn't—we had no agreement with the whole industry. These were the people that had agreed together to [95] do this at the suggestion of the Food and Drug Administration.

* * *

[96] Q. And after your submission of the Master File in May of 1941 did Lilly participate with any other companies in any joint efforts of any kind regarding Diethylstilbestrol? A. None.

* * *

[101] Q. Would you attend medical association meetings where these subjects were discussed? A. No, I didn't attend any of the meetings of the obstetrical group, but since all of these involved the medical type problems and problems with the physiology of pregnancy, these were discussed at general meetings of—medical meetings and at meetings of the Endocrine Society and I think in some of the meetings on internal medicine.

Q. During the period of time we're now referring to, that is, '41 through '47, did you attend the Annual Endocrine Society meetings? A. In that period I attended all of them.

Q. What about the AMA meetings? A. I attended all of the AMA meetings in that period.

Q. Did Lilly send out any DES to investigators during that period of time for use particularly in accidents of pregnancy? A. Yes, we did.

Q. Do you remember approximately how many? A. I don't think it was more than a dozen, actually. It was not very many in number.

Q. Now, who were the pioneers in this field of using, first, natural estrogens and then DES for women who were threatening to abort or had a history of miscarriage? A. Well, the pioneers in this were George Smith and his wife in Brookline, Massachusetts.

* * *

[106] Q. Were they [George and Olive Smith] connected with Harvard in any way? A. I believe they had appointments at Harvard, yes.

Q. What was the general standing and reputation of Olive and George Smith in the medical and scientific community in those days? A. They were in the absolute top bracket of researchers on endocrine problems.

Q. Now, then you have started to tell us about Priscilla White and the Joslin Clinic.

First of all, what is the Joslin Clinic? A. The Joslin Clinic was started by Elliot Joslin—I don't know exactly when, but I think it was in the late teens—and as far as I know it was the first clinic to specialize in the treatment of diabetes.

Q. And what— A. Dr. Joslin was without any question the leading expert on diabetes.

* * *

MR. BAUER: Q. What is the standing and reputation of Dr. Joslin and the Joslin Clinic in the treatment of diabetics?

[107] THE WITNESS: A. It was certainly the top clinic in the United States and many considered it the top clinic in the world in the treatment of diabetes.

Q. Now, who is Priscilla White? A. She was one of their staff members, a physician who specialized in pregnant diabetics and in their offspring.

There was both a practical and a theoretical aspect to her interest. She—all the people at the clinic were interested in the hereditary factor in diabetes.

Q. What is the general standing and reputation of Priscilla White in the treatment of diabetic—pregnant diabetics? A. She is one of the very top authorities on the subject.

Q. All right. Would you go ahead with your relation of the manner in which the Joslin Clinic and Priscilla White enter into this picture. A. Diabetic women are especially prone to these accidents of pregnancy. The incidence is much higher in them.

Before insulin came along, a diabetic, pregnant diabetic woman almost never had a live baby and the mortality during pregnancy was extremely high. Insulin changed that so that the women suffered very little greater risk

and there were some live babies, but the mortality was still high.

Q. When you say the mortality was high, do you have any idea of the figures or statistics, percentage of loss of babies by pregnant diabetic women?

* * *

[115] Q. At this period of time, that is, 1947, did you have any idea or any evidence from any source that there might be any danger to the fetus from the use of DES— A. No.

Q. —in a pregnant woman? A. No.

Q. At the time of the approval of DES for accidents of pregnancy, was that in 1947? A. '47 in the fall, as I remember.

Q. How long had DES been on the market at that time? A. Approximately six years.

Q. And what type of experience were you knowledgeable about concerning the effects of DES on women who had taken it and offspring during that six-year period of time? A. Actually, I believe that the use of it in pregnancy had begun in 1940, if not toward the end of 1939, and since Priscilla, one of her particular interests was in the children of diabetics, these children had been followed with great care and in great detail and she had published follow-up studies of patients by that time. Some of these had been—were five years old.

Q. And had there been any reported abnormalities of the [116] genital tract in these children that Priscilla White had given DES to their mothers? A. None.

There tends—the children of diabetic mothers who are born alive without any hormone treatment of any kind tend to be overweight and to have certain temporary alterations from normal. These you expect.

And in the offspring of the mothers who had taken Stilbestrol, there were no differences. They tended to

be a little heavier, but nothing that we considered abnormal and certainly their external genital tracts were perfectly normal.

And those that had died in utero and had been delivered dead, of course all those that were—where the patient gave permission and that kind of situation should have been about a hundred per cent, they were carefully studied and they were—

* * *

[118] Q. All right. Proceed, please. A. Those that had been born dead that were autopsied, they found no evidence of abnormality of the internal genital organs either.

Q. Was that information communicated to you and to Lilly? A. Yes.

Q. And did it—was it some of the information that was taken into account by you and Lilly in submitting a supplemental new NDA— A. Yes.

Q. —for use in accidents of pregnancy? A. It was.

Q. While the "A" Forms will be in evidence at the trial of this case, and without getting them out to read them to the jury in this deposition, can you tell us from your recollection what the basic indication was in your package literature and in your "A" Forms for use in accidents of pregnancy?

* * *

[119] Q. * * * First of all, would you tell us what an "A" form is?

[120] THE WITNESS: A. "A" Form is the term that Lilly used for the piece of literature that was given to doctors to inform them about the drug and how to use it. Anything that was used in that way we called an "A" Form.

Q. Was it something that doctors could write in to get from Lilly or was it— A. When a drug was first marketed, they, the representative who went in to tell the doctor about its availability was supposed to leave one with the doctor—

Q. I see. A. —if the doctor had the slightest interest in prescribing it, and it was also available to any physician on request.

Q. And then, for the record, would you tell us what package literature was as far as Lilly was concerned? A. Packaged literature is a piece of literature that goes with the medication, is packaged with it, and it was Lilly's policy to include that only in preparations that were to be used by the doctor himself. We kept that kind of thing out of packages that were to go directly from the pharmacist to a patient. So, for most purposes this limited the packaged literature to ampules which the doctor himself would inject.

* * *

[135] Q. And is it the final 12 companies that were involved? A. Evidently, yes, this is the final 12. Obviously two more entered.

Q. Would you read those into the record, please? A. Abbott Laboratories of Chicago;

Armour Laboratories of Chicago;

Ayerst, McKenna & Harrison, Rouses Point, New York;

George A. Breon & Company, Kansas City, Missouri;

Charles E. Frosst & Company, Richmond, Virginia;

Eli Lilly and Company, Indianapolis;

Merck & Company, Rahway, New Jersey;

Sharp & Dohme, Philadelphia;

E. R. Squibb & Sons, New York;

The Upjohn Company, Kalamazoo, Michigan;

Winthrop Chemical Company, New York;
John Wyeth & Brother, Philadelphia.

* * *

[151] Q. If asked, could you tell me what the DES looked like in pill form? A. They were white tablets.

* * *

[158] Q. Were you aware that patents were in fact issued to Lilly regarding DES? A. I have understood so.

* * *

[207] MR. BAUER: Defendant's Exhibit 1.

MR. CHARFOOS: Q. Is it not true in fact that the meeting that started at ten a.m. on January 28, 1941 wasn't called by the FDA at all? A. My recollection was that it was.

Q. Is it not true, sir, that in fact that no meeting took place at the FDA and that there was indeed a hotel meeting at that date called by Mr. Frailey? A. Yes. I see I misremembered. This says, "Hotel Washington". I misremembered that.

Q. And as a matter of fact, is it not true, sir, that on January 13th, some almost two weeks before you and about eight or nine other gentlemen in the drug industry received a personal letter from Carson B. Frailey, executive vice president, American Drug Manufacturer's Association, asking you to be in Washington, D. C. on January 28th, 1941 to discuss, I am sorry, 1941, yes, to discuss your future activities in the field of DES? A. Of course this letter is a letter to Mr. Carter of Abbott Laboratories.

Q. Would you agree, sir, that on the bottom it shows a copy to you? A. It shows a copy to me. I did not recall how I found out about this meeting. I would assume that a similar letter would be it.

Q. Exhibit No. 7, is it marked? A. Marked Plaintiff's Exhibit No. 7.

Q. And who were the gentlemen that were invited to that meeting by Mr. Frailey? • • •

• • •

[218] Q. In additional to gathering or at least being the recipient of this clinical data from the various companies plus your own in-house work, did you not also as we have discussed earlier, make an effort to uniformize or put into standard nomanclature the criterion for what DDS would be like chemically? A. All I did was to collect the data that was supplied by the different companies. No standards were issued to them. They were only told what methods would—we relayed to the other companies what the Food and Drug Administration said about the kind of, the standard of measurements.

Q. What does that mean, sir? A. For instance, one of the criteria at that time was melting point of the substance itself and of certain kinds of chemical derivatives. And I don't know about this of my own knowledge, but I understood from the chemists that even, that this, a combination of this kind was likely to give a unique pattern, so if you knew the melting points of a substance and various derivatives, you could say with some assurance what the primary substance was. And there are various methods of determining [219] melting points.

Now, it may seem that it melts or it doesn't, but apparently it isn't that simple. So one has to use a standard method in order to obtain uniform results.

And they insisted that measurements be made according to the method of the United States Pharmacopeia.

Q. Who were they? A. The Food and Drug Administration.

Q. How was that communicated to you? A. This may have come through Mr. Frailey. I don't recall at the moment how it came to us.

Q. Anyway, it is not true that you sent out a letter to the other companies involved suggesting that they follow the UFP standard in filing their application? A. Yes, that's correct.

Q. What was or what is the meaning of the UFP standard? A. Well, I tried to explain that there are various methods of determining melting points in the United States Pharmacopeia, which is the official—I was going to say publication, but it's more than a publication, it is a committee composed of pharmacists and physicians, some chemists who are knowledgeable in drug matters, and they are the people who draw up these books known as the United States Pharmacopeia and this is an official group. And it is an official book that defines the standards for various drugs. And in connection with that, they have run up methods of assay of various kinds which are—they adopt [220] as the standard methods.

Q. From a layman's viewpoint or in other words from a practical viewpoint, could you not then have just looked in the USP book and seen the standard printed by them for this drug? A. No, because the drug was not yet in the United States Pharmacopeia. What was standard, what the Food and Drug Administration was talking about was using the standard procedure for determining the melting point of the drug. At that time the Food and Drug Administration, I don't believe had, it had itself adopted a standard melting, had defined what the melting point of the pure chemical should be by the USP method. What we were talking about here is merely a method, and not the result that was to be obtained by that method. We merely asked the companies to communicate to us so that we could relay as part of the master clinical file the companies' own determination of the actual melting point, using the United States Pharmacopeia method, and as I pointed out, the reason for this,

why these two should go together, was that since the data were being pooled, it was of some scientific importance to establish that all the doctors who had received drug from different companies were using in fact the identical same compound.

* * *

[228] Q. Doctor— A. Now the reason for these, in one instance very strong recommendation, is that the Food and Drug Administration had told us very positively that they would require uniform labeling in these regards.

Q. And who was to receive the final packages of these labels and inserts before— A. That would go directly from each company to the Food and Drug Administration.

* * *

[237] Q. At any time did you personally participate in the preparation of the 1947 new drug supplement? A. I prepared the clinical part.

Q. Did you work with anyone else? A. On that?

Q. Yes, sir. A. Not that I recall. That is not on an equal basis. Naturally I had a secretary.

Q. Sure. Did you in any way, form or manner intercommunicate with any other drug companies on this subject? A. Not at all.

Q. Did other drug companies file similar application?

* * *

THE WITNESS: Well, obviously they did at one time or another because I believe the companies eventually marketed the drug for these same indications.

MR. CHARFOOS: Q. Do you know who the first company is that did? A. I had the impression that Lilly was, but I don't really know for sure. There should be records concerning that.

* * *

[239] A. Well, our first interest was in getting more information and if the experience was favorable and we felt the safety factor was favorable, then we would market it or try to.

Q. And in filing your clinical section you had to com—comply with part one, which is already in Plaintiffs' Exhibit No. 2, is that not correct? A. That is correct.

Q. Would you read the requirement under part one, please? A. "One. Full report of all investigations which have been made to show whether or not the drug is safe for use." Do you want beyond that?

Q. Is that the end of number one? A. That is the end of the first item. Do you want the rest?

Q. Well, which ones would you participate in other than one? Probably number two? A. No. I would be responsible for part of six. "Six. Five copies of each label and other labeling to be used for the drug." It would be the other labeling that I would be responsible for. I would not be responsible for any of the rest of it.

Q. Oh, sure. A. But one and part of six.

Q. Now, let's into the record read number two—I am glad we are not going too long, two through number five. A. Two reads: "A full list of the articles used as components of the drug."

Three: "A full statement of the composition of the drug."

Four-A: "A full description of the methods used in the * * *."

* * *

[245] Q. Under your request at any time did you ask anybody in Lilly to carry out any specific animal studies with specific direction to review the effects of this drug on the offspring of a pregnant animal? A. I do not—I do not recall whether any such studies were made or not.

Q. Certainly none were brought to your attention? A. No, I wouldn't say that.

Q. Within Lilly? A. I don't recall whether any were or were not.

Q. All right. You did not request any? A. As far as I can recall, I did not.

Q. In context then may I assume that you were in some large part relying on the 5,000 cases that you had submitted plus the in-field experience of the drug being given to mothers now for what, almost five or six years, as to the safety of the drug for the use to the mother? A. We were not relying in any way on the earlier experience.

Q. All right. A. As I related before, the work on what would be called the pathological physiology of accidents of pregnancy had been started in the middle of 1930 and treatment with actual estrogens had already been started before diethylstilbestrol came along.

Q. To use it in frame of reference, we are now referring to material you submitted to the FDA.

• • •

[246] THE WITNESS: I'm trying to explain the history of the investigation of the hormonal treatment of accidents of pregnancy, and diethylstilbestrol came along after the general pattern of the pathological physiology was moderately well understood and after experiments and treatment had been undertaken with natural estrogens.

• • •

A. I'm trying to explain what is the sequence of what went on here. So that diethylstilbestrol was used in place of a natural estrogen because of the obvious advantages which we have already—I have already gone into. So that this progressed, and by 1947 this—diethyl-

stilbestrol had already been used in human beings in this condition—in these conditions—

• • •

THE WITNESS: In accidents of pregnancy, had been used for some seven years and the patients and their offspring, especially in the case of Smith and White—

MR. CHARFOOS: Q. Wait a minute, Doctor. I'm going to interrupt you, I'm sorry.

• • •

[247] MR. CHARFOOS: Q. My question is limited to the point of whether or not you had supplied to the FDA any materials other than what was found here in this exhibit and whether or not you in fact had relied further on material, to-wit, the 5,000 cases that you had supplied back in 1941. My understanding as to part one, this exhibit represented what you supplied to the FDA and, two, that you did not rely on the 5,000 cases? A. That's right.

• • •

• • • These patients had been followed, at least some of them, for six years so that we felt that this material was quite an adequate experience to establish both efficacy and safety.

Now, one uses animal experiments when you think that the animal provides a model in which you can duplicate or nearly duplicate the human condition; and the fact of the matter is [248] that there was not then and —well, I can't say for sure, I doubt if there is now, if they have discovered an animal model that in any way parallels the accidents of human pregnancy. So that there is no animal model that you can use.

MR. CHARFOOS: Q. Are you saying—

A. For—

Q. Are you saying that you had to experiment on living human beings and their fetuses? A. In a sense, yes, but it is easy to misunderstand a simple yes answer.

Q. Well, as a matter of fact, isn't it true that the FDA wrote back to you when you supplied that material, Dr. Hines, or to Lilly on this, that the whole area is experimental? A. Well, obviously it is experimental until they say it isn't.

Q. Even when they wrote back descriptively describing what you proposed to do, is it not true that they said as far as they were concerned the whole area was experimental as distinguished from being not well recognized and well accepted as you just indicated in your speech? A. I don't recall any such letter. Do you have a copy?

• • •

[259] Q. None of that was known to the Lilly Company when it came out with DES for accidents of pregnancy; you didn't know what was going to happen to these people, did you? A. In the sense that you don't ever know when you give a medicine to a person, you don't ever know with absolute certainty what's going to happen.

Q. As a matter of fact, in this particular case when you first offered it for accidents of pregnancy you did not know what was going to happen with any certainty, let alone absolutely certainty? A. That is—that question, I think, places the whole thing in the wrong context.

Q. You just— A. When we came out with this there had been six years of experience with the use of this drug in accidents of pregnancy. There was a body of clinical information available. No claim was ever made that every women who took this was going to carry her baby to term. There was never any claim of that sort.

Now, I think it is very strained because you can't say which woman will carry to term and which won't. I think it's a very strained interpretation of the word experimental to—to term this whole program experimental because of that fact.

Q. Did you participate in the data that was used for the insert in the packaging, in drawing up the data?

* * *

[279] Q. Would you explain to the jury, please, Witness, what a detail man or woman, if there are detail women,— A. At that time there were no detail women. I wouldn't know about now.

Q. What detail men were, jobwise, in the '40s and '50s? A. They—they were men, practically all of whom, very few exceptions, were trained pharmacists whose job was to call on practicing physicians and tell them about the current status of Lilly's drugs.

* * *

[282] Q. And the purpose of that detailing was to attempt to indicate to that doctor that he should prescribe Lilly's DES for accidents in pregnancy? A. Not uniformly, only where it was indicated. And his bible in that was the Defense Exhibit 4 at the beginning.

Q. Your Form A? A. Yes.

MR. BAUER: A Form.

THE WITNESS: A Form we called it.

MR. CHARFOOS: Q. You certainly had—that A Form that you gave to the doctor was given to him by a detail man is what you are saying? A. In some instances.

Q. How else would you distribute it? A. If he wrote in and asked for information we would send him this.

* * *

[326] Q. My point is that it is your position that the doctor should not have relied solely on your input, or your A-Form, on accidents of pregnancy. He should have some additional knowledge about this drug beyond what you from Lilly told him? A. Exactly. Just as we assume that he has a general knowledge of medicine. We feel we are quite correct in assuming that he has a great deal of information that we don't have to give him, and, as a matter of fact, there's a good many, there are a good many kinds of information which he would feel insulted if we had given him. He'd say, "Well, for heaven sakes, I already know that."

Q. Your position then is that a reasonable and prudent doctor in 19— A. '47.

Q. —'47 through— A. Yes.

Q. —1950, 1955— A. (Witness nods head in the affirmative.)

Q. —should have known that there was a carcinogenic potential in using this drug in pregnant ladies? A. No, because there was no such thing that had been established or even suggested. What he should know was that it did produce cancer in certain kinds of animals and that therefore a question naturally arose as to the possibility.

Q. We agree then really. I said that there was a potential. A. Well, to me "That there is potential" has to me, in the meaning of the scope of possbility in the sense that it has [327] in some instance already happened. Now, that's my interpretation of potential. Possibility was purely a theoretical one.

Q. With the doctor to decide whether or not it would occur? A. No. At that time, certainly, and I'm only talking about up to that time, there'd been no demonstrated incidents related to man, to, in human beings as being related to estrogenic therapy. Now, certainly—

Q. You are sure of that? A. Well there had been case reports in which cancer of the breast and other

organs had developed in women who were taking diethylstilbestrol, but, of course, they have automobile accidents and develop cancer of other things and have heart attacks and so on. But a single or even two or three associations does not establish any relationship.

* * *

[377] A. Yes. Now, I—that—that was the question, but let me just be sure here. One, the single case report by Auchincloss, or Auchincloss, was of cancer of the breast.

Q. All right. None of them talked about cancer in the offspring of women who took DES, did they? A. No.

Q. Now we turn to the second category of articles that Doctor—Mr. Charfoos—started to call him Doctor.

MR. CHARFOOS: Thank you, Counsel.

MR. BAUER: Q. —had produced yesterday, and they all deal with animals, is that correct? A. They all deal with animals.

Q. Have you had an opportunity to read or review briefly these articles that deal with animals that Mr. Charfoos produced? A. I reviewed them. I can't say I read every word of each article, but I reviewed them. I reviewed them carefully.

Q. Were these animal studies that are reported in the literature helpful to you and Lilly in determining whether or not to use diethylstilbestrol in pregnant women in view of the circumstances that existed in 1947— A. No.

Q. —that you previously mentioned? A. They were not helpful.

Q. And why was that, Dr. Hines? A. Most of all of them dealt with nonpregnant animals. They were in species that are quite unlike the human in their reproductive physiology. The doses were for, almost univer-

sally, extremely large, massive. Could you read over that list I gave * * *.

* * *

[392] Q. Just read that portion which indicated the FDA had been out talking to practitioners themselves. A. This letter is dated May 29, 1947 and has to do with the application for tablets diethylstilbestrol 25 milligram, which were especially tailored for use in accidents of pregnancy. And it says, "We have reviewed the material which you have submitted with your application and conferred with many of the outstanding experts in the fields of obstetrics and endocrinology."

Q. All right. Why did you select the Smith and Smith dosage schedule to put in your 1947 A Form? A. There were several factors that all worked together. We felt that the Smiths had been working with accidents of pregnancy and studying the excretion of the estrogen and progesterone in the urine longer than anyone else. They had the best background. They had been using estrogenic treatment longer than anybody else, and we—so we felt that they had the best background for determining a dosage schedule that would match the—and would provide as accurate a replacement therapy as could be devised.

Now, furthermore it had the—also the advantage that it was relatively simple and it also was—represented a rather middle ground in the recommendations of various other people that had—that had been using the same general kind of treatment.

* * *

[414] THE WITNESS: As a matter of fact, although I can't provide the records, I know that they were studying the fetuses that didn't make it, and in those it would be

absolutely routine to do cellular studies. These tissues were studied under the microscope.

MR. CHARFOOS: Q. And is it not true, sir, that not only is there no data to show any studies or any test, but that at least two articles that you referred to in your "A" Form dealt with the subject, one, first of all, of warning of the potential of cancer, and that is Dr. White herself, Priscilla White, and I'm referring to the article that you recalled that's called in your "A" Form "Pregnancy Complicating Diabetes", published in September of '43; that's one of the articles you're familiar with, isn't it?

THE WITNESS: A. I would have to look at it to be sure. She published a number of articles.

* * *

[428] MR. CHARFOOS: Q. Or any of them?

THE WITNESS: A. Oh, yes. In one of their articles Priscilla White reported, she and a co-worker reported on follow-up studies on live—babies born live. She had a number of publications. I don't recall exactly which ones, but it's there.

There was that much experience. And as time went on, there were additional years of experience which certainly as long as I followed the subject, and that's as long as I can speak for, continued to reinforce the evidence that there was no harm to mothers or babies from this treatment.

* * *

Squibb's Answers to Requests for Admissions 237a

No. 74 030 070 NP

ANSWERS TO REQUESTS FOR ADMISSIONS BY E. R. SQUIBB & SONS, INC.

NOW COMES the defendant, E. R. SQUIBB & SONS, INC., and for its Answers to the plaintiffs' Requests for Admissions says:

1. Don't know.
2. No.
3. Yes.

A. April 28, 1947.

* * *

E. R. Squibb & Sons, Inc.
By /s/ William P. Cooney
W. P. Cooney
Its Attorney in Fact

* * *

Subscribed and sworn to before me this 25th day of May, 1976.

/s/ Donna L. Bonior
Notary Public Wayne County, Mich.
Acting in Oakland County, Mich.

My Commission Expires June 13, 1977

DEPOSITION OF DR. THEODORE G. KLUMPP ON OCTOBER 20, 1976

* * *

[8] In 1936 I was granted a year's leave of absence to the Federal Food & Drug Administration. At the end of the year I had hardly completed the tasks that I was asked to perform, so I stayed on another year and was then made Chief Medical Officer of the Food & Drug Administration.

Q. Doctor Klumpp, for a frame of reference, can you tell us the date that you graduated from Princeton University? A. Yes. 1924 from Princeton; 1928 from Harvard Medical School; the Lakeside Hospital from '29 to—well, my internship went through '29 and from '29 to '32 I served there in 19—at Lakeside Hospital, and in 1932 received the appointment as an Administrator and Associate Physician at the Yale University Medical School.

Q. While you were at Yale, Doctor Klumpp, did you actually practice medicine in addition to your teaching responsibilities? A. Yes, I did.

Q. Was that at the New Haven Hospital? A. Yes.

Q. Would you tell us your age, please? A. Seventy-three.

* * *

[11] Q. Was there a change in your position with the FDA at that time? A. Well, I mentioned that I was made Chief Medical Officer, and then in 1938 was promoted to the position of Chief of the Drug Division.

Q. Was that the position that had formerly been held by Doctor Durrett? A. That's correct.

Q. And after that change came about, what was Doctor Durrett's responsibility with the FDA? A. Well, about shortly thereafter, the amendments to the Food &

Drugs Act of 1938 became partly, in part effective, and Doctor Durrett, as a result of that, was assigned to the new Drug Section, which was a sub-section under the Drug Division.

• • •

[16] Q. You already mentioned briefly the start of the regulatory history of drugs in the United States, which first occurred in 1906.

Would you describe for us briefly what change was made by the Act in 1938, basic provisions of that Act? A. The most important provision of the amendments of 1938 concerned new drugs, and a new section was added to the Food & Drugs Act, called the New Drugs Section, Section 505 of the law.

Q. Well, what did that provide for, basically? A. Section 505 provided that no new drug could be marketed, placed on the market, without prior approval of the Food & Drug Administration.

Q. Were there certain requirements of the Food & Drug Administration, of the drug companies applying, before approval of a New Drug Application? A. Yes, indeed, there were.

Q. Could you just run through the basic requirements that a drug company had to follow in filing a New Drug Application, after the passage of the 1938 Act? A. The companies were required to submit data first on the [17] chemical identity of the drug, control data, and its strength qualities and purity, and methods of manufacture, the raw material, the raw materials that were used in the process of manufacture, and in some instances the source of those raw materials.

The applicant was also required to submit data on studies that had been made to establish the—the safety of the drug and a sample of the proposed labeling to be

used in marketing, labeling and packaging to be used in the marketing of a preparation.

Q. These studies that were required to be filed showing the safety of the drug, were they normally referred to as clinical studies or clinical investigations? A. Yes, to a great extent.

Q. And just briefly what does that term mean, "clinical investigations" or "clinical studies?" A. Well, the only what that one can determine whether a drug is or is not safe is by studies made by responsible and, not infrequently, outstanding authorities in the given field of therapy.

* * *

[21] Q. (By Mr. Bauer, continuing): Would you continue on with your answer, please? A. It was very small. We had at that time about a half a dozen medical officers in the Drug Division and two of them in the New Drug Section.

Q. Doctor Klumpp, before we get to the approval of DES or diethylstilbestrol, would you tell us, please, if there were any similarities between the way the DES approval was handled and the way the approval of sulfathiazole was handled by the FDA?

MR. CHARFOOS: Objection to relevancy, but go ahead.

A. Yes. There were unique resemblances between those two New Drug Applications and the way in which they were handled.

Q. (By Mr. Bauer, continuing): Let me interrupt you right there. As a frame of reference, was the sulfathiazole approval and the applications made for approval, was that prior to the DES approval? [22] A. It was.

Q. All right. Would you continue, please? A. With the—with receiving four applications, I think that number

is correct, for sulfathiazole, it was considered at that time by the officials of the Food & Drug Administration, that the handling and consideration of the data received would be facilitated if these applications were all put together and the term "Master File" was coined at that time and these applications were all part, then, of a Master File.

Now, the important point about that is that clinical reports or reports of the studies made on sulfathiazole were fragmentary with respect to each application, and in some instances, not adequate in the judgment of the Food & Drug Administration, to permit the New Drug Application to become effective, but in their totality, they were sufficient, so that we were not so much interested in whether one or a dozen firms marketed the preparation; we wanted to know what the clinical experience was and that experience, we felt, should be applied to each one of the New Drug Applicants. That also was the case with respect to the preparation DES.

* * *

[24] Q. Let's talk for a few minutes, Dr. Klumpp, about the diethylstilbestrol situation.

Can you tell us just briefly what diethylstilbestrol is? Explain it in just common ordinary lay terms, if you would, sir. A. That is going to be a little difficult, may I comment.

Diethylstilbestrol was the first synthetic, fabricated estrogen up to that time. The source of estrogens were from human beings and animals and it was in scarce supply and very expensive.

Diethylstilbestrol was a cheap, or a chemical that could be made at a low cost in comparison with the cost of manufacture and ultimate—and in sales price of the natural estrogens.

Q. Would you tell us, please, what is an estrogen? A. An estrogen is a substance which has the effects of the natural female sex hormone, which is as probably everybody knows, secreted by the ovaries and also other tissues.

* * *

[26] Q. From your knowledge of the practice of medicine at that time how was natural estrogen administered to women that needed this replacement of estrogen in their body? A. It was administered and could only be administered by injection.

Q. And, generally, where would they give the injection? A. In the buttocks.

Q. Were there any complications that occasionally arose from that type of administration of estrogen? A. Yes.

Q. What were they?

* * *

A. First of all the injections were painful. Secondly, they required the patient to come to the offices, to the office of the physician, her physician for the injections, which was a great inconvenience, and, thirdly, there resulted—the injections led to the formation of an abscess or abscesses at the site.

* * *

[30] Q. Can you tell us approximately how many such new drug applications were on file with the Food and Drug Administration by the end of 1940?

* * *

A. There were ten new drug applications by the end of 1940.

Q. Did a number of these new drug applications cause any problems with the FDA and its staff handling

them and trying to make the determination as to whether or not they should be granted? A. Yes, indeed it did. It caused what we felt was an overwhelming problem to consider each one of them separately, and as an entity.

Q. Was Doctor Durrett the one who initially had the task of reviewing all of these new drug applications? A. He was.

Q. Sometime near the end of 1940, did you have discussions among the personnel at the Food and Drug Administration about the best way to handle these ten new drug applications for DES that had been filed? A. We had such discussions, which began as the new drug applications poured in. There was no problem when we had one or two, but when they started multiplying it [31] posed a very serious administrative problem.

Q. What were the discussions that were had at the FDA about the problem of handling all of these new drug applications for DES?

* * *

A. (Continuing): I participated in those discussions.

Q. Well, I want you to tell the Court and jury about them now, please? A. We were convinced that it was in the public interest for us to require or make a strong request that the clinical data be joined together, those data that were submitted by each manufacturer, and that the total package of the data be used to consider each individual application for new drug approval.

Q. Did you have any problem with the FDA in, for instance, keeping track of all of the various investigators whose reports would be submitted with these new drug applications? A. As the numbers grew we did have a serious problem.

Q. What action did the FDA take as a result of these conferences among the various officials of the FDA in re-

gard to conveying that concern to the drug companies involved?

Would you just tell us about that, please? [32] A. We first made the proposal—

* * *

A. (Continuing): Mr. Campbell, Doctor Durrett and I principally, and our staffs met on a number of occasions to consider this problem, and we came to the conclusion that it would be in the public interest to have all this clinical material pooled and that pooled material was referred to as the master file as it had been in the sulfathiazole case. That information, that conclusion that was arrived at by the officials of the Food and Drug Administration was discussed with the representative of one of the drug associations and that representative was Mr. Carson Frailey.

Q. F-r-a-i-l-e-y? A. Yes, C-a-r-s-o-n, Carson Frailey. We were interested [33] in learning what the reactions of those manufacturers who had submitted new drug applications and perhaps others who had it in mind would be to such a proposal.

Mr. Frailey reported back to us that they didn't like it one bit, and—

MR. CHARFOOS: (Interposing): I will object to what Mr. Frailey said, witness, and I think, again, because this is not with a Judge, I should make that objection.

Q. (By Mr. Bauer, continuing): Go ahead. A. Mr. Frailey reported to me that the manufacturers didn't like the idea one bit and he suggested that some of them would refuse to go along with it. So, as a result of that, the officials of the Food and Drug Administration, I was one of them, called a meeting of those manufacturers who had submitted new drug applications and informed them formally and officially that we desired them to do this.

Q. Was that meeting on December 30, 1940? A. I think that was the date, approximately.

Q. And do you remember where the meeting was held? A. It was held in Doctor Durrett's office.

Q. All right. You personally were not present at that meeting, as I understand it? [34] A. I was not present.

Q. You had talked to Doctor Durrett about this meeting before he attended it, is that true? A. Yes, I had discussed it with him. I was in full accord with it and the only reason I was not present was that I had other duties at the particular time that were urgent.

Q. All right. Were you advised afterwards of the response of the companies at that meeting to the insistence of Doctor Durrett and the FDA about filing this clinical data in a joint fashion? A. The attitude of the companies—

* * *

A. (Continuing): To this proposal was all too clear.

Q. And what was the basic attitude, if you can tell us? A. They didn't want to do it.

Q. And what motivation was given the companies to proceed to do this despite the fact that at least some of them didn't want to? A. Well, Mr. Bauer, we realized at that time that we scarcely had the authority to force them to do this, but that we made it clear to them that if we had to consider each new drug application separately that that [35] would consume a lot of time, and it would seriously delay our consideration of the new drug applications and their possible approval.

Q. Did you, and by "you" I mean also the FDA, consider that this demand of the FDA for the companies to file their data jointly was in the public interest? A. Very much so.

Q. Let's move to the subject, Doctor Klumpp, of what the FDA did independently of the data that was submitted by the companies to support their new drug applications.

Would you go through and outline what type of action the FDA itself took in trying to determine basically whether DES was safe and whether it should be approved? A. We considered this an exceedingly important new drug application, and for that reason we felt it important in the public interest to obtain as much information as we could.

For that reason we, several, Doctor Durrett, Doctor King and I, visited outstanding experts in this field and discussed the whole subject with them.

Q. Were these, some of these experts people that the FDA had requested the companies to contact or were they people that the companies had not contacted but for [36] some reason the FDA desired to contact itself? A. It was both. Some had been contacted by the companies. They too were trying to seek out the outstanding experts but there were others that, in whose judgment we had confidence, and we went to see them.

Q. Was this the normal way in which the FDA would go about checking on the safety of a drug at that time by consulting the outstanding experts in the country? A. This was, at that point, distinctly unusual.

Q. In that this was more than the FDA normally did? A. It was. We were authorized by law to consider the data submitted by the applicant for new drug release, and it was not incumbent on us to make independent investigations at that time.

Q. You mentioned previously that this appeared to be a very important drug for which this approval was sought. Can you just tell us why this appeared to be an important situation? A. The very fact that within the span of a year we had received ten new drug applications, and knew of more that were coming along, indicated that this was an

important preparation. It also had an important medicinal effect, and we wanted to be sure that that effect was under the law safe and efficacious as well.

[37] Q. Doctor Klumpp, if DES was found to be safe and approved, would that mean that great numbers of women would be helped or could use this preparation as opposed to the rather limited numbers of women that have the natural estrogen available to them? A. Yes.

Q. You mentioned, Doctor Ernest King. He was one of the medical officers of the FDA? A. Yes.

Q. And can you tell us approximately how many of these experts in the United States that Doctor King interviewed in trying to make this determination? A. He was sent to interview about a dozen experts in the field, which he did.

Q. Would he then report the substance of those interviews to you for evaluation? A. Yes.

Q. Did Doctor Durrett also do some of the same kind of work, that is interviewing some doctors? A. He did.

Q. And did you yourself interview doctors or talk with them on the telephone? A. I did.

Q. And could you just tell us, approximately, the number of [38] experts that you yourself consulted on this subject of the safety of DES, if you recall? A. Oh, I recall the parameters of that. I would say that the best recollection I have is that I consulted with about a dozen experts in this field.

Q. All right. During the time that the approval of DES was under consideration by your agency, the FDA, were there any of the doctors that indicated any reluctance to give their blessing to the approval of diethylstilbestrol?

* * *

A. Yes. There was reluctance expressed on the part of two or three investigators.

Q. Do you happen to remember the names of those investigators and where they were located? A. Strangely enough they were all in the New York area, and they were Doctor Rephael Kurzrock and Doctor Ephram Shorr, and Doctor Geist.

Q. Could you spell that last name? A. G-e-i-s-t.

Q. What statements did these doctors make indicating a reluctance to give blessing or approval of DES initially? What was their concern? A. Their concern arose from the fact that their use of [39] DES resulted in nausea and vomiting in some patients, not all of them, and they were concerned that that might be an indication of toxicity, particularly liver damage.

Q. All right. As the results of interviews from other experts came into the FDA, and as the clinical investigations came in, was there an explanation found for the nausea and vomiting that these two or three doctors in New York had reported? A. Yes. The picture became very clear, and that was that they were using doses that were too large, too great for those individuals and that, and the others found when they used a smaller dosage they did not obtain such symptoms.

Q. All right. Would you tell me, Doctor Klumpp, please and, of course, the Court and the jury, approximately how many experts around the country were consulted either by the FDA or the various drug companies in gathering information regarding the approval of DES? A. It was the largest number of experts that had been—whose findings and studies had been made available to the Food and Drug Administration up to that time, about one hundred in number.

Q. Other than the two or three New York doctors that at least [40] initially expressed some concern about the nausea and vomiting, what was the report from the other doctors, the other experts around the country? A.

The reports of the other doctors were favorable and on our direct questions to them as to whether in their judgment these new drug applications should be made effective, they responded in the affirmative, yes.

Q. Was that one of the inquiries that was made specifically to these doctors, whether or not in their opinion, in their use of the drug in clinical trials they felt the drug should be approved for general use? A. We were resting in our considerations of DES on the safety and efficacy, and our questioning was, do you consider this, number one, a useful and efficacious preparation, and, number two, a safe one in the doses that they used.

Q. And did—I understood you previously to indicate that all but the two or three New York doctors indicated that they thought it was a good, safe product, that should be approved by the FDA? A. That's correct.

[41] Q. (By Mr. Bauer, continuing): Dr. Klumpp, before the break we were talking about the opinions of the various experts that the FDA had consulted on an opinion in this case. In addition to consulting experts, did you attempt to follow whatever medical literature there was on the subject at that time? A. I did.

Q. There's one thing I think I forgot to bring out. While you were at the FDA, were you also teaching outside at some medical school and practicing medicine? A. I was.

Q. Would you tell us about that, please? A. I was licensed to practice medicine in the District of Columbia and appointed Adjunct clinical professor of medicine at George Washington University Medical School and served as attending physician at the Gallinger Municipal Hospital, which was the municipal hospital of the District of Columbia.

Q. And did that encompass the actual practice of medicine during a portion of your time while you were with the FDA? A. It did.

• • •

[45] Q. And was the evidence there convincing that there was no liver damage? A. Those studies revealed no liver damage.

Q. And did the FDA officials, including yourself, come to the conclusion that DES posed no problem as far as the liver was concerned? A. We came to that conclusion.

Q. Let's move on to the subject of the actual approval of DES by the Food and Drug Administration.

Can you tell us approximately how long it was after the March 25th, 1941 meeting that the FDA determined among its representatives that DES should, in fact, be approved? A. There was a gradual convergence of thinking on the part of all those that were interested in the application and had some background of information toward the view that this new drug application was approvable. It, I would say—you asked me for a date, I believe, or time—

Q. (Interposing): An approximate time that you received this conclusion. A. Yes. So, I can't tell you a date, because it wasn't a precipitated thing, it came gradually. I would say by the end of April and the early part of May the officials [46] of the Food and Drug Administration, and we had discussed it among ourselves repeatedly, had come to the conclusion that the data were adequate to establish the safety and efficacy of this preparation.

Q. Was everyone at the FDA in full accord and agreement with that decision? A. They were.

Q. Including Dr. Durrett? A. Yes.

Q. Now, had he left the employment of the FDA sometime during the early part of 1941? A. Yes, he left in the first part of 1941.

Q. By that time had you talked with him specifically— A. (Interposing): Yes.

Q. (Continuing): —about his feelings about the approval of the DES? A. Yes.

Q. Before he left? A. Yes, very much so.

Q. All right.

* * *

Q. (By Mr. Bauer, continuing): Would you tell us, Dr. Klumpp, in your judgment, having been at the FDA from the time [47] the Drug Act of 1938 was passed, the quality and quantity of the submission by the drug companies for diethylstilbestrol? A. We were very much impressed with the data that had been—that was submitted in support of these NDAs. They were superb reports. They were—there were more reports than we had ever received before in any preparation. We—we had about 53 to 5500 case reports from a hundred investigators, and not only was the quantity greater than any we had had before, but the quality was also higher than anything we had had before.

Q. Can you give us any general idea of the numbers of clinical reports that had been submitted in connection with other drugs prior to the approval of DES?

* * *

Q. (By Mr. Bauer, continuing): For instance, can you recall—I think you told us about 700 for sulfathiazole? A. Yes.

Q. Was that the biggest clinical data submitted prior to DES, do you remember? A. To the best of my recollection it constituted a high at that time.

Q. What, the DES? A. No, the 700 case reports that were submitted in support [48] of sulfathiazole.

Q. Well, do you recall any other drug prior to the approval of DES that had as many as 700 case reports? A. I cannot.

Q. When did you leave the FDA, Dr. Klumpp? A. In June, 1941.

Q. While the decision for approval wasn't announced until a few months later, had it been made at the FDA at that time? A. It had.

Q. Had you talked about this subject with Dr.—with Mr. Campbell—excuse me—before you left? A. Yes. It was one of the pending matters that was there and we discussed it before I left, discussed it many times.

Q. Do you have any knowledge as to why there was, say, a two or three month delay between the time the FDA had actually made up its mind to approve DES and the announcement of it in September? A. Yes, I do.

Q. Would you tell us about that, please? A. Up to the time of making a decision that the drug was—the preparation was safe and effective, there seemed to be no reason to go into other matters. For example, we [49] thought it was very important that the identity of each preparation be the same and to establish the fact that we were not dealing with different drugs but we were dealing with one DES, and that the samples of those drugs used in the clinical investigations were identical, we sent the laboratories of the FDA in to the job of studying these preparations, and it was only when those studies were concluded that—and all the labeling had been submitted and gone over that the Food and Drug Administration felt entitled to take action.

Q. All right. You have mentioned Carson Frailey previously. Would you tell us, if you haven't already described his position, what position he held with the American Drug and Manufacturers Association? A. He was the executive secretary of that organization and in that position served as a liaison between the manufacturers of DES and the contemplated manufacturers and the Food and Drug Administration.

This—this arrangement saved us a great deal of time and effort. We could relay what we wanted to Mr. Frailey, we could find out what we wanted through Mr. Frailey. Instead of making, by this time, 12 telephone calls to 12 different companies, we just had to call Mr. Frailey, and he made the 12 telephone calls. [50] So that he was very helpful to the—our agency, and we learned, too, long before this time that he was a reliable individual and we could depend on his word and he did what he said he was going to do.

Q. Am I correct in recalling that the FDA either did or may have set up the two meetings that we have discussed, that is, the meeting of December 30, 1940 and the one on March 25th, 1941, through Carson Frailey? A. Yes.

* * *

Q. You mentioned the name of one outstanding expert that you consulted, I believe, Dr. TeLinde. Could you mention the name of several others? I'm thinking particularly— A. (Interposing): Yes, Dr. Elmer Severinghaus of the University of Minnesota.

Q. Is that Minnesota or Wisconsin, do you remember? A. Minnesota, I think.

* * *

[72] Q. (Interposing): That is why I said, "In part". In other words it was a two-way street, in effect? A. But we had no desire to approve any new drug application that was, on the face of it, insufficient.

Q. Be that as it may, ten to twelve companies did get together and did file a Master Application? A. I don't know that they got together.

Q. You are aware of the— A. We asked them, we in effect, demanded that they file a joint clinical report.

MR. BAUER: I think for the record, Mr. Charfoos, it was not an application. It was a Master File of joint clinical trial data, as I think you are aware.

MR. CHARFOOS: Yes.

MR. BAUER: And I think you used the word "application". Each individual company filed their own NDA pursuant to regulations.

Q. (By Mr. Charfoos, continuing): Did you become familiar with a group called "the small committee"? A. Yes. I was aware of the—that group, and in my testimony I named the members of it.

* * *

[74] Q. And, therefore, is it not true, sir, that was between ten and twelve drug companies working in some kind of organized grouping to file a master clinical study, that it would follow that you would expect to have more clinical studies with that many drug companies? A. We—we made certain requests for additional studies to the whole group, but, again, I have no knowledge that there was any combination of companies or that they combined.

We simply asked them to file these things jointly.

Q. All right. My only point is that you talked about the large number of clinical studies. My point being, well, with ten to twelve companies you would expect more clinical studies, as, say, versus one company filing an application for a new drug? A. We insisted on more studies, yes, sir.

Q. Now, are you aware that on December 30th, 1940, that all the original companies that had filed a request for an NDA withdrew their request? A. I am very well aware of that because they didn't withdraw their New Drug Applications; we asked them to withdraw their New Drug Applications.

Q. All right. And what was the reason for asking them to [75] withdraw it, sir? A. Because the law specified that we were to have 60 days to consider a New Drug Application, and if we had not been able to come to a conclusion at the end of 60 days, we were to ask for 180 days additional time.

Now, it was very clear to us that we were going to run into the end of the 180-day period and in those days we took the legislative mandate very seriously and did not want to go on beyond that time.

Q. How did you communicate this to the drug companies, individually or through a single person? A. Primarily through Carson Frailey.

Q. All right. Now, you have indicated to us, I believe that you personally had occasion to consult with one or more recognized independent experts in this field prior to the approval being allowed for the original DES application; is that correct? A. That is correct, yes.

Q. And, as I understand it, you talked about seeing approximately a dozen, I believe? A. Yes.

Q. Of these dozen, one or more were independent? In other words, they had not been supplied by the drug company? A. That was the only way they could get DES.

[76] Q. Was what? A. Was from a drug company.

Q. I'm sorry. I thought there were certain independent investigators, who had nothing to do with the drug industry, that you had talked to? A. They were all independent investigators, or we wouldn't have received their reports, but as some had been approached by the drug companies specific—to study DES specifically for that company, and there were other investigators who were studying the product, not at the request of a drug company, but on their own.

Q. Is it my understanding, then, that in order for them to be studying it, they would have had to be in contact with a drug company? A. To get the material, yes.

Q. And would the drug company give it to just anybody that asked for it? A. Not to anybody who asked for it, certainly not.

Q. There had to be some criterion? A. Some criterion of confidence.

Q. And who was the person or persons who decided whether or not the first doctor to ask for the drug was quote-unquote, competent? A. The drug department of the drug company.

[77] Q. Now, you have indicated in your direct testimony that you personally did meet with some of these men? A. I did.

Q. Yes. And could you tell us, I guess, in fact, we have been supplied this morning by counsel with a copy of the documents that you used to refresh your memory.

* * *

[78] A. Yes.

Q. (By Mr. Charfoos, continuing): Now, my question to you, sir, is: In that group of papers was there any reference to any doctor or doctors that you had interviewed personally? A. Yes, there was.

Q. And which ones are those? A. Doctor Kurzrock, and I don't have any of Shorr's memorandums here, but Ephram Shorr was another one. Doctor Severinghaus of the University of Wisconsin.

Q. Did you go over there? A. No. I talked to him by phone.

Q. Did you go out of town to interview any of these— A. (Interposing): Yes.

Q. (Continuing): —doctors? A. Yes. I went to New York to interview these two. I went to Chicago.

Q. All right. Anybody else? A. And I interviewed Doctor Plass of the University of Iowa.

* * *

A. I interviewed Doctor Davis in Chicago. I interviewed Doctor Robert Lewis of New Haven, and I went [79] to New Haven.

Q. (By Mr. Charfoos, continuing): Now, would any of those doctors—is that it? A. And Doctor Engle.

* * *

Q. (By Mr. Charfoos, continuing): To the best of your memory, have you listed the ones you remember now? A. I interviewed Doctor Salmon. * * * I interviewed Doctor Koskin(?) in Chicago, and there were others that don't come to mind immediately.

Q. All right. Of the group that you do remember talking to, were any of them, in your discussions, working with the drug as a preventative in the accident of pregnancy? A. I didn't interview for that indication and I don't know whether they were working on that.

Q. It never came up in your discussions? A. No.

Q. Were any of those doctors, if you remember, were any of them testing it on pregnant ladies? A. Not to my knowledge.

* * *

[99] Q. Were you aware at that time that there was a potential carcinogenic effect from the use of DES?

MR. BAUER: From what? It is an abstract question. I object to the form of the question. You have not identified as to any particular entity.

MR. CHARFOOS: I have asked my question. I am asking if he was aware?

A. I was aware of some reports in animals, small animals, rodents to that effect, yes.

Q. (By Mr. Charfoos, continuing): Did you carry out any—I better change that. Did you or did the FDA carry out any independent study as to the potential danger from that area to human beings? A. We relied on the studies and opinions of our experts and the Food and Drug Administration was not called upon either by the law or by regulations to perform any studies on its own.

Q. Do I understand then that you relied on the materials supplied to you by the drug industry?

* * *

Q. (By Mr. Charfoos, continuing): Did you rely on any studies other than that which were put into the new [100] drug applications? A. I have testified, Mr. Charfoos, that we relied on our own studies of the work being done by those whom we considered the outstanding experts in the field.

Q. Did any of them carry out testing as to the carcinogenic potential of this drug? A. Yes.

Q. Who? A. Doctor Edgar Allen and his associate, Mr. Strong, Doctor Strong, and there were a good many reports of an effect in inbred species of mice of a stimulation of the growth of tumors, but I should also point out at the same time that tumors grew spontaneously in these inbred strains of mice.

Q. Doctor Allen's studies were published studies? A. Yes.

Q. Were there any studies that you at the FDA requested to be done as an independent research project to determine potential problems from this drug in terms of carcinogenic effects? A. As I mentioned before, we had full confidence that the outstanding experts in this field would have knowledge of those studies and would take those reports into account and would advise us of their views, * * *.

* * *

[130] A. Yes. Doctor Edgar Allen, with Edward Doisy, was the discoverer of the female sex hormone while he was at the University of Missouri. He subsequently came to Yale University Medical School while—while I was there and I became acquainted with Doctor Allen, subsequently very friendly with him and he was my best friend there on the faculty, and he and I were sailing companions for many years, even after I left Yale and was with the Food & Drug Administration. We went sailing every summer together.

Q. Were you—excuse me. Were you finished, Doctor? A. Yes, I have finished. Thank you.

Q. Were you generally aware of the animal studies that Doctor Allen had conducted and written about in the literature involving rodent strains, inbred strains of mice and that sort of thing? A. I was generally aware of work he was doing with Gardener and Strong in the laboratories at Yale, and we did discuss that work repeatedly.

Q. What about the articles that Doctor Allen wrote; are you aware of the fact that he co-authored some articles with Doctor Gardener? [131] A. Yes.

Q. And just briefly what was Doctor Gardener's specialty and where was he located? A. He was at Yale, too, I think. I did not know Doctor Gardener personally.

Q. All right. And did you know of the work that Doctor Edgar Allen had done involving natural estrogens and testing them on rodents, laboratory animals, inbred strains of mice and that sort of thing? A. I was generally familiar with his research activities at Yale.

Q. Were you also generally familiar with the work that Doctor Allen did involving a testing of diethylstilbestrol on laboratory animals? A. Yes.

Q. And inbred strains of mice? A. Yes.

Q. And that sort of thing? A. We discussed those.

Q. And during the time that DES was under consideration for approval by the Food & Drug Administration, did you have numerous discussions with Doctor Edgar Allen? A. Yes.

Q. About the animal work that he had been doing and had done? [132] A. Yes. That was the subject of discussion, a matter of interest to both of us.

Q. Then, Doctor Allen knew that DES was up for approval, so to speak, by the FDA? A. Oh, yes. He knew it very well.

Q. As a result of these conversations that you had with him, were there ever any reservations whatsoever expressed by Doctor Edgar Allen, about the approval of DES for use in human beings, regardless of what the animal work had shown that he had done with DES?

* * *

A. He expressed no reservations.

Q. (By Mr. Bauer, continuing): At the time of the seeking the approval of DES for the initial occasion that you have mentioned, you said there were initially ten companies and then I believe it became twelve before the actual approval? A. Yes.

Q. Is that correct? A. That's correct.

Q. That certainly wasn't even a major part or the entire pharmaceutical industry, was it, Doctor Klumpp? A. No. Twelve out of an industry of almost 200 major companies, that's all, twelve.

* * *

[137] Q. Now I would like to ask you, Doctor Klumpp, if you know of the circumstances of the inclusion of that permission clause in the New Drug Application of Eli Lilly and Company? A. In the first place, we wanted to have a written expression of permission to utilize the data of one company and apply it to a New Drug

Application of another company. We could not simply go on a verbal understanding. We had to have that in writing.

The language here in this statement was not dictated by anyone in an administrative position of the Food and Drug Administration. We simply told, through Mr. Frailey, the industry that we wanted a permission clause to accompany each New Drug Application, and what happened after that, I do not know, except that this appeared.

Q. Well, were you aware at the time that the New Drug Applications were approved or about ready to be approved [138] for the original 12 submitting companies, that there were other companies that intended in the future to file New Drug Applications for the use of diethylstilbestrol? A. I would say it didn't take a great deal of foresight to be able to divine that there would be other New Drug Applications.

Q. And was it your thought, as you have expressed, that you wanted to have the vast clinical data that you have described, that was submitted by the 12 companies, available for the FDA's use in looking at and judging the approval of future applications by drug companies for permission to market DES? A. That was our intention. We didn't feel that we could utilize this data only for those New Drug Applications that we had on hand; that it had to be applicable to all New Drug Applications, whether they came in then or later.

Q. Was that a benefit, in your judgment, to the FDA and to the public? A. Yes, we think it was.

* * *